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# Assessment of children emotional state during robot-based gait rehabilitation: from patients' self-evaluation to bio-signals processing

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## Abstract:

Robot-assisted therapy is nowadays an established intervention for gait rehabilitation of patients with neurological disorders. However, traditional approaches aim to improve treatment efficacy focusing on the system function, neglecting psychological factors that can greatly contribute to its outcome.

Therefore, the present Master thesis aims to objectively characterize patients' emotional state during the Lokomat therapy through the analysis of bio-signals such as blood volume pulse and electrodermal activity recorded with the E4 wristband, therapists' evaluations and patients' self-evaluation. In particular, the first objective is to develop a signal processing and emotion-related features extraction pipeline. Second objective is to investigate whether these parameters show correlation with therapists' evaluation and patients' self-evaluation about their emotional state. The final objective is to assess whether children's emotional state changes throughout the rehabilitation period. To this purpose, 16 patients who received Lokomat gait training at IRCCS Medea were enrolled in the study.

Signal processing algorithms were implemented: BVP signal was filtered from motion artefacts exploiting the acceleration data provided by the E4 device, while a stationary wavelet transform was used for the EDA signal. Time and frequency domain parameters were then extracted for both signals.

Correlation analysis between biological data and questionnaire responses shows that the EDA frequency parameters are the most indicative features of patients' emotional state. Statistical analysis of the acquired data, compared between the two sessions analysed, suggests that walking with the Lokomat system is perceived as a positive experience by the subjects.

Based on preliminary results, it can be concluded that it is possible to investigate the subjects' emotional state during the rehabilitation session through the bio-signals recorded by the E4 wristband.

Future developments may introduce some modifications to the protocol to automatically identify any stressful situation and adjust the therapy not only to patients' physical performance but also to their psychological condition.

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## 1. Introduction

### 1.1. Robotic rehabilitation

Rehabilitation is defined by the WHO [1] as *“a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment”*. Gait abnormalities due to neurological disorders negatively affect patients’ quality of life, therefore, the aim of rehabilitation must be helping them to be as independent as possible in everyday activities enabling and improving their social participation and quality of life.

Conventional gait therapies consist in the execution and repetition, with physiotherapist’s manual assistance, of motor exercises such as stretching and strengthening activities and overground walking training, aimed to improve endurance, balance, coordination and range of motion in treated patients [2].

Conversely, robot-assisted therapies have been widely used for gait rehabilitation, since they aim to reduce the required therapists' physical effort and time, improve the reproducibility of physiological gait kinematics and increase the intensity, volume and difficulty of task-oriented motor exercises in a high-level safe environment with respect to above-mentioned techniques [3].

In this field, robotic rehabilitation systems can be classified into stationary and overground walking systems [3].

Overground walking systems help the patients to practice safely gait and perform daily-life movement (for example sitting), following the patient's intention of movement: the robot allows the subjects to move under their own control rather than through predetermined patterns (unlike stationary devices). For this reason, they can be potentially used also at home since they are more compact and lightweight when compared to stationary systems [4].

An example of overground system is the Ekso™ device: it attaches to the users' torso with a backpack and, for each leg, to their thigh, shank, and foot. It exploits a gestural-based interface so that sensors embedded in the device make the system respond to real muscular input from the user [5].

Stationary systems consist of a fixed body weight support (BWS) structure combined with a moving ground platform (i.e. treadmill or programmable foot end-effector).

Programmable footplates guide the distal segments of the lower limbs, simulating the phases of gait such as stance and swing phase and reproducing gait trajectories. These devices are not characterized by the presence of an exoskeleton structure, thus support for knee joints is not provided, which may be challenging for patients with moderate or severe disability [3].

Among end-effector devices there is the GaitTrainer, a rehabilitation robot designed for repeated practice of a physiological-like gait (i.e ratio of 60:40 between stance and swing phases). The machine allows a partial up to complete support of the feet movement based on the patient's ability [6].

Conversely, treadmill gait approaches use BWS system and exoskeleton structures connected to the patient's lower limbs. Exoskeletons are electromechanical wearable devices that operate simultaneously on the human limb (although with possible friction with the limb movement) replicating joints movement and augmenting muscle strength [3,4]. To this purpose, limb exoskeletons should have adequate and physiological degree of freedoms also to minimize patients' discomfort.

Example of treadmill-based robotic device are LOPES and Lokomat.

The Lower Extremity Powered ExoSkeleton (LOPES) initially developed at the University of Twente for stroke patients, is a combination of an exoskeleton robot for the legs and an end-effector robot for the pelvis. It allows both 'patient-in-charge' mode, where the patient is able to move unconstrained and actively, and 'robot-in-charge' modality in which the robot is controlled to guide the patient, who moves passively [7].

Lokomat, designed and developed by Hocoma is an active lower limb exoskeleton that combines body weight support system and treadmill training for gait rehabilitation.

A more detailed description of Lokomat that is used in the present study is given in the section 2.2.

Several studies analysed the effects of robot-assisted technology in adults: the systematic review conducted by Mehrholz and colleagues found evidence of the efficacy of robotic-assisted gait-training devices, combined with conventional gait treatment, in regaining independent walking ability of post-stroke patients with respect to the use of only conventional therapies [8].

On the other hand, the current evidence regarding the clinical effectiveness and applicability of Lokomat training in paediatrics is weak and inconsistent [9]:

Borggraeve et al. investigated the effect of Lokomat therapy in children and adolescents with bilateral spastic cerebral palsy (CP) on their standing and walking performance demonstrating that after a relatively short programme of robotic-assisted treadmill therapy their performance improved. More in detail, the study showed that the severity of motor impairment could possibly have an effect on the improvement achieved: patients with moderate/severe cerebral palsy achieved less improvement after the trial with respect to mildly affected patients, due to a lower potential of re-gaining motor function over time compared to mildly affected [10].

Wallard et al. proposed a randomized controlled trial to explore the effect of robot-assisted gait training with Lokomat on the dynamic equilibrium control during walking in cerebral palsy affected children, whose motor impairment severity was classified as moderate (level II in the Gross Motor Function Classification System-GMFCS). The experimental group was treated with Lokomat training, while the control group only participated in exercises with a physiotherapist. Postural strategies were then evaluated both for the treated and control group, at the beginning of the trial and in the post treatment phase, confirming that robotic gait rehabilitation presented beneficial effect on postural and locomotor functions [11].

Beretta and collaborators retrospectively evaluated the effect of robotic rehabilitation, combined with physical therapy, in children with CP and acquired brain injury (ABI), with different levels of motor impairment (GMFCS levels I-IV), finding positive results but with substantial differences between ABI and CP subgroups, with greater improvement for children with ABI [12].

Van Hedel and colleagues retrospectively analysed the effect of Lokomat training (combined with conventional physiotherapy) on children with CP [13]. Differently from [10], the study concluded that the greatest benefit may be for children with more severe functional involvement (i.e GMFCS IV). In addition, results indicated that robot-assisted training in combination with other therapies could improve walking performance in everyday life, while no effect on walking endurance was found.

## 1.2. Importance of the psychological aspect in rehabilitation

Traditional approaches aim to improve treatment efficacy focusing more on the system function and gait motor function recovery (e.g walking endurance, walking speed, replication of a correct gait pattern), neglecting psychological factors [14]. Patients' mental engagement can be an important factor in successful rehabilitation, however, assessing patients' psychophysiological condition can be difficult since the therapists can rely only on their personal experience and not on objective methods.

Only recently, studies have highlighted the importance of the psychological factors in improving rehabilitation efficacy.

Qualitative methods were used by Zhong and collaborators, who designed a specific questionnaire in order to investigate what are the main valuable characteristics of rehabilitation robots that in users' perspectives could enhance treatment efficacy with rehabilitation robots, like Lokomat. Eight psychological strategies were proposed and grouped into three macro-categories: robot design (F1 natural and compatible human-robot movement, F2 friendly robotic appearance, F3 attractive interface), function design (F4 adaptable task difficulty levels, F5 intelligent conversation, F6 connecting individuals, F7 performance feedback), and patients' expectation (F8). From questionnaires responses emerged that natural and compatible human-robot movement (F1) and performance feedback (F7) were most valued by users, suggesting that these factors could be considered in developing new robot-assisted rehabilitation techniques for a more successful therapy [14].

[15] proposed a qualitative study to investigate the expectations and experiences of children with CP related to the Lokomat training, with the aim of helping therapists in planning therapies but also to help them to support parents in making decisions regarding therapy. Semi-structured interviews were conducted both with parents and children also to assess children's habits and interests so that therapists can 'personalise' the treatment to the patients. Children's impression about the Lokomat itself were collected: some children were initially scared by the appearance of the Lokomat even if during the session this feeling seemed to decrease. Comfort-related problems were also reported such as skin problems or interruption of the session due to adjustments/calibration. Authors suggested that it would be useful to warn parents and patients in advance about the procedure to avoid patient's frustration. In addition, the interactive screen seemed to be fun initially, even if they reported getting bored after a while. Some of the patients positively emphasized the fact that challenging tasks were present, while others believed that the robot did all the work, not being challenged enough. Finally, it was highlighted how the therapist's presence and care towards the patient was a determining factor for the result, on the other hand, some patients were not sure about the effectiveness of the therapy in the future.

Alternatively, psycho-physiological state and mental engagement were evaluated objectively with quantitative methods: [16] focused attention on the importance of the active participation of the patient to improve the efficacy of the training with assistive robot (Lokomat) which, in this way, combined the patient's physics, intentions and actions. Subjects' psycho-physiological state was evaluated with heart rate, electrodermal activity, skin temperature and breathing frequency recordings.

Koenig and collaborators aimed to determine whether a patient was mentally engaged during the training in order to maximize motor learning during rehabilitation [17]. The purpose was to objectively identify different levels of patients' mental engagement (i.e under-challenging, challenging and overchallenging) with ECG, breathing, electrodermal activity (EDA), and skin temperature recordings. Understanding the emotional state of the patient allowed to adapt the challenging level of the task and maximize the result. Indeed, from motor learning theory, it is known that the learning rate is maximal at a task difficulty level that positively challenges and excites subjects while not being too stressful or boring [18]. A task that is too easy for the subject will be perceived as boring, but at the same time, a task that is too difficult will overstress the subject, thus, an optimally challenging task should induce maximal mental engagement and optimal physical participation.

### 1.3. Technologies for HRV and EDA measurements

Heart Rate Variability (HRV) and electrodermal activity (EDA) are considered the most informative markers for psychophysiological and emotional states, according to [17,19,20].

Traditional technologies for HRV measurements are ECG recording with the use of surface electrodes [21]. For EDA measurements, two adhesive electrodes are typically placed on the participant's feet, palms, or fingers, as in [22].

These technologies provide more reliable measures; however, some limitations are present such as the complexity of the system and obtrusive measures, because of probes that can restrict patients' mobility and interfere with the subject's task affecting the therapy outcome.

Wearable devices, in which photoplethysmograph (PPG) sensors and EDA electrodes are embedded, can also be used in this context, given several advantages such as ease of use and non-obtrusive, continuous and long-term measurements. On the other hand, these devices may be more sensitive to signal noise and motion artefacts.

To address this issue, [23] removed noise from the PPG signal, without deteriorating it, exploiting its quasi-periodicity. A periodic moving average filter was applied to the signal: the signal was segmented into periods and resampled to have all segments with the same sample period. Finally, these segments were averaged over their entire length to generate motion artefact free PPG signals.

In [24], a method was developed for recovering the PPG signal exploiting a MEMS accelerometer embedded in a wearable ring device. The signal detected by the PPG sensor was seen as a combination of true signal and the distorted component, which was estimated by an adaptive filter in response to the measured acceleration signal provided in real time. Finally, the estimated distortion was subtracted from the bio-sensor output obtaining the filtered data.

Similarly, in [25] an adaptive filter technique was applied to reduce the motion artefact of the PPG signal recorded with a wristband sensor device, again exploiting acceleration data to estimate the noise component.

As for EDA artefact removal, an heuristic method was developed in [26], where data were considered as artefacts if the signal increased more than 20% per second or decreased more than 10% per second. This method was then verified by visual inspection. Similarly, [27] manually set thresholds for the amplitude, slope, and width of an electrodermal response (EDR), and discarded peaks that did not fit these criteria.

However, heuristic methods may not generalize beyond those contexts therefore they cannot be applied to our data.

Otherwise, a study was proposed in [28] where two independent EDA sensors were placed on both the ankle and the wrist of the subjects. In this way, artefacts were detected by looking for epochs where abnormality of the signal (e.g low signal, unusual rapid increase or decrease of the signal) were present only in one of the two resulting signals.

Other approaches, as the one implemented in [29], performed automatic artefacts detection with a supervised machine learning classifier. Expert EDA researchers labelled artefacts following criteria such as: a peak which did not show exponential decay, depending on the context (e.g. if two EDRs were overlapped the first one did not show an exponential decay but this was not considered an artefact); quantization error with  $\geq 5\%$  of signal amplitude; sudden change in EDA due to movement (acceleration data were exploited to this purpose); electrodermal level  $\leq 0 \mu\text{S}$ .

Similarly, [30] identified artefacts adopting criteria such as: EDA out of range (0.05-60  $\mu\text{S}$ ); EDA changed too quickly (slope out of -10, 10  $\mu\text{S}/\text{sec}$  range); temperature out of range (30-40  $^{\circ}\text{C}$ ) suggesting that the sensor was not being worn correctly.

Finally, [31] applied a stationary wavelet transform to the EDA signal to identify the artefacts, comparing the outcome with experts' opinion to validate their method. The efficacy of the selected technique was proven comparing it with low pass filtering and exponential smoothing methods.

At my knowledge, it appears that no estimation of psychophysiological states with both quantitative and semi-quantitative methods has never been performed in children with neurological disorders during Lokomat rehabilitation therapies.

Therefore, the aim of the present Master thesis is to objectively characterize the emotional state of the patient before and throughout the therapy with Lokomat, combining the monitoring of the activation of the autonomic nervous system (ANS) through the analysis of bio-signals, such as blood volume pulse and electrodermal activity, with the therapist's evaluation and patients' self-assessment. In particular, the first specific objective of the study is to develop a (semi)automatic algorithm for the extraction of emotion-related features from patients' bio-signals, recorded with the E4 wearable wrist medical device (Empatica®, Milan, Italy). The secondary objective is to investigate whether the extracted features correlate with the therapists' evaluation, collected during the rehabilitation session, and/or with the patients' self-evaluation, collected before and after the treatment, about their emotional state. The final objective is to assess if and how children's emotional state changes throughout the rehabilitation period.

## 2. Material and Methods

### 2.1. Test subjects and acquisition protocol

The project in which the present Master thesis is included, aims to enrol in the study 40 subjects, who are receiving treatment with Lokomat (at Istituto Scientifico IRCCS Eugenio Medea), as prescribed by the reference clinician. To each of them an ID code was assigned to guarantee anonymization.

Data acquisition with the E4 wristband was performed in two separate sessions, at the beginning and at the end (among the last five sessions) of therapy course planned for the patient.

For the purposes of the study, it was of interest to tag the different events of the session (start and end of the active training, completion of questionnaires, fastening and securing procedures and games).

To avoid interruptions during the rehabilitation session, it was decided not to ask the physiotherapist to press the apposite button on the E4 wristband. An alternative solution was found: when the patient entered the room, he was required to wear the Empatica wristband on the non-dominant arm. In addition, a computer video recording was started and lasted for the entire experiment.

For synchronization purposes, exclusively for the identification of the initial and final tags, the patient pressed the button on the E4 bracelet, which was framed by the camera during this procedure.

In this way, the Empatica sensor recorded, in UNIX time, the instant when the button was pushed so that the start and the end of the session could be easily recognized.

During the video recording, every other event was tagged by emitting a bright flash with a pointer near the computer camera.



Before the training, patients were asked to fill in an *ad hoc* questionnaire in which they were asked about their feelings at that moment with the aim of investigating their emotional state before the treatment adopting mainly VAS (visual analogue scale) evaluation scales.

This was followed by the rehabilitative exercises on the Lokomat system, during which the physiotherapist involved and a researcher were asked to fill in an *ad hoc* questionnaire to collect a reliable evaluation about patients' different levels of anxiety, activity, persistence.

At the end of the rehabilitation, patients were asked again about their emotional state through the VAS *ad hoc* questionnaire to assess changes in their psychophysiological state after the Lokomat session. Concurrently, an additional questionnaire, designed with more appropriate questioning techniques for younger children [15], was proposed: it is a drawing, where the patient is portrayed during the rehabilitation activity, in which they could express their feelings related to the session through colours and sentences in the empty (or with sentence starters) clouds of thought (Figure 1).

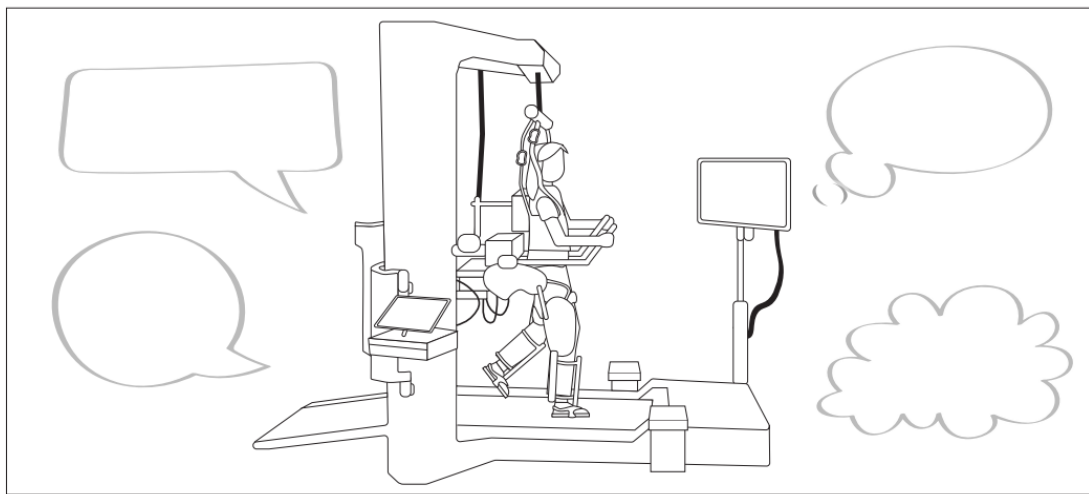


Figure 1: Drawing-like questionnaire.

VAS questionnaires and therapist's evaluations are described in detail in the section 2.5.

## 2.2. Lokomat driven gait orthosis

Lokomat (Hokoma) is a driven gait orthosis (DGO), that combines body weight support system and treadmill training, that is widely used in gait rehabilitation (Figure 2).

The patient is secured into the exoskeleton system during fastening procedure with harness around the hip and straps around the legs, while elastic foot straps lift the patient's feet passively to prevent foot drop [17].

Hip and knee joints of the orthosis are moved by two drives for each leg [32], controlled by a real-time system to adjust hip and knee joint angles so to replicate more physiological gait pattern.

In addition, the patient is fixed with a BWS system, that allows to off-load part of the weight of the patient ensuring stability and safer environment during walking process.

The body weight unloading is proportional to the phase of rehabilitation and to the mobility of the patient: at the beginning of training the BWS system can bear up to the 60%–80% of the body weight, percentage that is reduced with time so to adapt to the patient's performance [3].

Constant feedbacks are provided to the patient to improve rehabilitation outcome [33]: during the rehabilitation session, exercises are mainly based on virtual games where objects, randomly distributed in a virtual environment, must be collected and/or avoided [3]. During these exercises, the Lokomat-augmented feedback module provides stimulating and interactive feedback projecting the results and game score on the monitor in front of the subject.

The proposed exercises can be adapted to the motor and cognitive skills of the patient: to challenge the patients and improve their performances, the physiotherapist can adjust the treatment parameters (e.g the weight support, the walking speed, the amount of assistance, intensity and difficulty of the exercises).

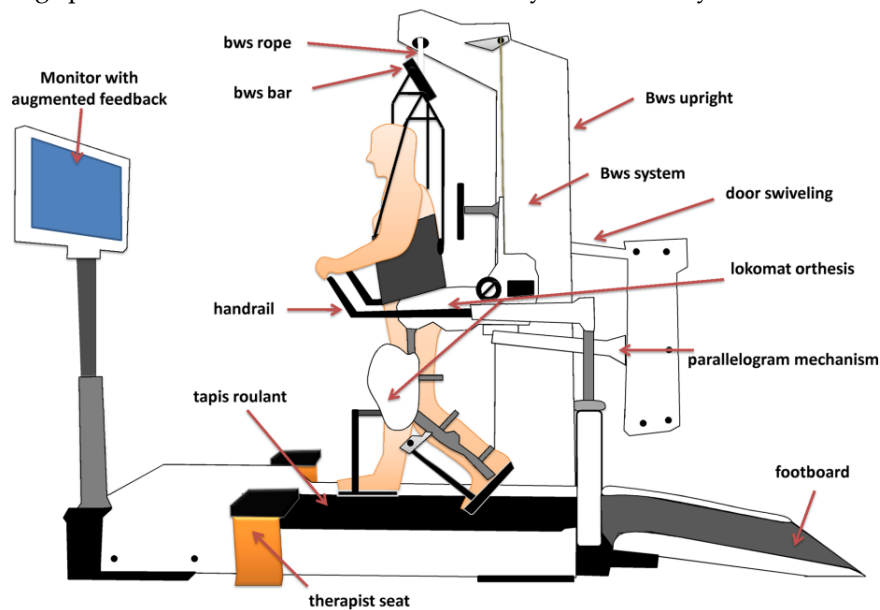


Figure 2: Lokomat structure [3].

### 2.3. Empatica E4 wristband wearable device

Physiological data were collected by E4 wristband (Empatica®, Milan, Italy), a wearable wireless device designed for comfortable, continuous, real-time data acquisition in daily life.

The technical characteristics of the device are taken from the Empatica E4 datasheet and the Empatica website [34]: the E4 wristband (Figure 3) is a class IIa Medical Device in the EU, according to CE Cert. No. 1876/MDD (93/42/EEC Directive).



Figure 3: Empatica E4 wristband [34].

It is equipped with different sensors:

- Photoplethysmogram sensor (PPG) that measures the blood volume pulse (BVP) signal, from which heart rate, heart rate variability, and other cardiovascular features may be derived. Sampling frequency: 64 Hz;
- Two silver-coated (Ag) electrodes that apply a small alternating current to the skin in order to measure the electrodermal activity (EDA). This signal may be useful to assess sympathetic nervous system arousal and to derive features related to stress, engagement, and excitement. Sampling frequency: 4 Hz;
- MEMS type 3-axis accelerometer, to capture motion-based activity. Sampling frequency: 32 Hz;
- Infrared thermopile, reading skin temperature. Sampling frequency: 4 Hz.



All the sensors are embedded in the device: the PPG sensor and the temperature sensor are on the bottom side of the device while the wristband holds the EDA Ag electrodes.

The wristband is also equipped with an event mark button which allows the recognition of different event occurred during the experiment.

The E4 is intended for the measurement of physical activity in patients over 5 years old also with neurological disorders. Thus, it can be considered a good solution for this project, since it is comfortable, non-obtrusive and familiar also for young patients.

As patients wear the E4 wristband during the entire rehabilitation session on Lokomat, the intense physical activity during the session may introduce motion artefacts in the recording data, complicating the stress detection process [35].

For this reason, data pre-processing of the data, described in section 2.4, was necessary.

### 2.3.1.Extracted bio-signals

The raw data recorded with E4 wristband are saved in the Empatica's Web Portal and they can be downloaded in .CSV format. In particular, five different signals are available:

- ACC - Data from 3-axis accelerometer sensor;
- BVP - Data from photoplethysmograph (PPG);
- EDA - Data from the electrodermal activity sensor in  $\mu S$ ;
- IBI - Inter beat intervals, which is real-time calculated when an 'ideal' BVP waveform is recognized;
- TEMP - Data from temperature sensor expressed in degrees on the Celsius ( $^{\circ}C$ ) scale;
- HR - Average heart rate values.

#### Acceleration data

Empatica E4 device have a MEMS type 3-axis accelerometer that measures continuous gravitational force (g) applied to the x, y and z spatial dimensions. The acceleration magnitude was computed as in Equation (1), scaled in a  $\pm 2g$  range and then filtered with a high-pass Butterworth filter (cut off frequency 0.1 Hz) to remove the gravity component.

$$A = \sqrt{a^2_x + a^2_y + a^2_z} \quad (1)$$

This signal was used in the pre-processing tool for recovering the corrupted BVP signal from motion artefacts, as explained in the section 2.4.2.

#### BVP signal

The E4 photoplethysmogram sensor includes a coupled red and green light-source and a photodetector; the lights produced by the Green and Red LEDs are oriented toward the skin and are absorbed by the blood in different ways. As blood perfuses through the capillaries and arteries after each heartbeat, a portion of the light is then reflected and measured by the Light receiver (Figure 4).

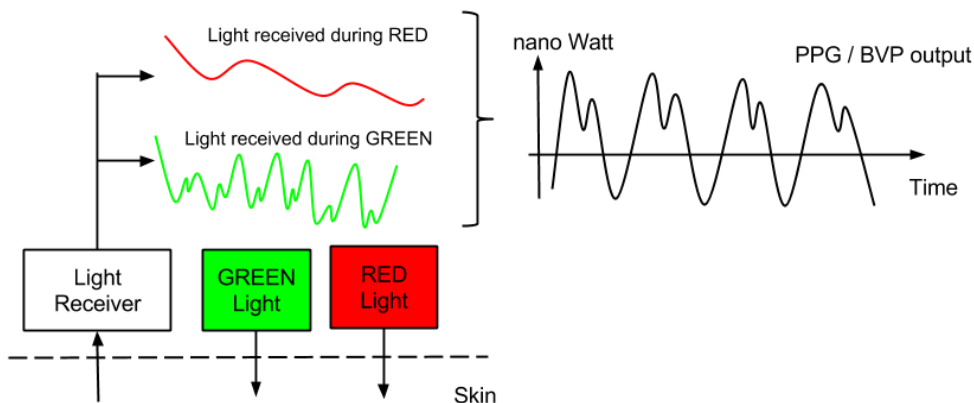


Figure 4: Working principle of Empatica photoplethysmogram sensor [34].

Typical PPG waveform consists of two components: the alternating current (AC) and direct current (DC) components. DC component refers to light absorbed by skin, tissue, bone, venous blood and non-pulsatile arterial blood and varies slowly with the respiration vasomotor activity and thermoregulation. Conversely, the AC components reflects changes in the blood volume that occurs between the systolic and diastolic phases of the cardiac cycle. The fundamental frequency of this pulsatile component is linked to the heart rate [36].

Figure 5 shows the ideal obtained BVP waveform where the characteristic points can be easily recognized: a local minimum called diastolic point, a systolic peak, and a dicrotic notch followed by a second wave.

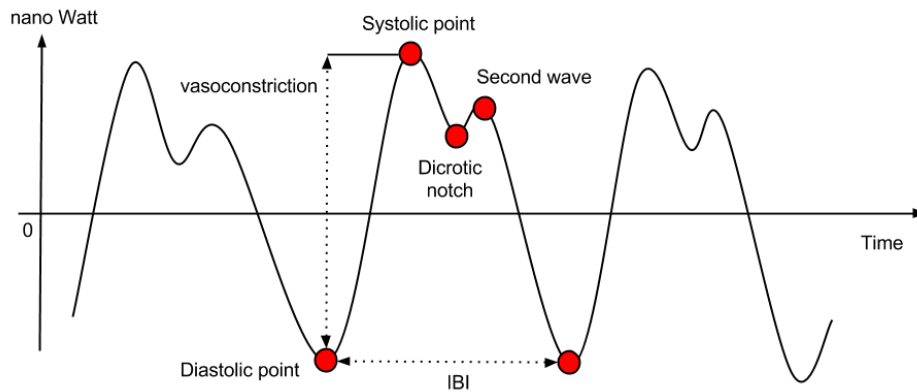


Figure 5: Expected BVP signal [34].

The Inter beat intervals (IBI) can be derived directly from the BVP signal as the time difference of two consecutive diastolic points.

The IBI spreadsheet provided by Empatica is structured in two columns: the former containing the instant where the diastolic point is recorded, the latter the temporal distance with respect to the previous one.

The extracted BVP signal was corrupted by motion artefacts due to the intense physical activity during Lokomat training. For this reason, the BVP signal was cleaned with pre-processing tools implemented during the thesis, as described in section 2.4.2

### EDA signal

Electrodermal activity (EDA), represents the variation of skin electrical properties as a reaction to sweat secretion, thus the EDA signal is a skin conductance measure ( $\mu\text{S}$ ).

Palmar and plantar eccrine sweat glands, innervated by the sympathetic nervous system (SNS), are considered responsible for psychological response, therefore changes in EDA are thought to reflect SNS arousal associated with emotion, cognition, and attention. In particular, under emotional arousal and stress, body sweats activity and skin conductance increases [37].

EDA raw signal can be divided into tonic (EDL: electrodermal level) and phasic phenomena (EDR: electrodermal response) as shown in Figure 6.

Electrodermal responses are recognizable as short-lasting variations of EDA signal that can be either elicited by an external stimulus, in this case they are called stimulus-specific electrodermal responses (S.EDRs), or spontaneous responses that cannot be traced to any specific stimulation, for this reason they are called nonspecific electrodermal responses (NS.EDRs) [38]. NS.SDRs are phasic increases in skin conductance that have the same appearance as S.EDRs (i.e they are both characterized by a rise from the onset to a peak, followed by an exponential decline).

In the present thesis the focus was only on non-specific responses, since during the Lokomat session there were no imposed and established a priori stimuli of which the response could be studied.

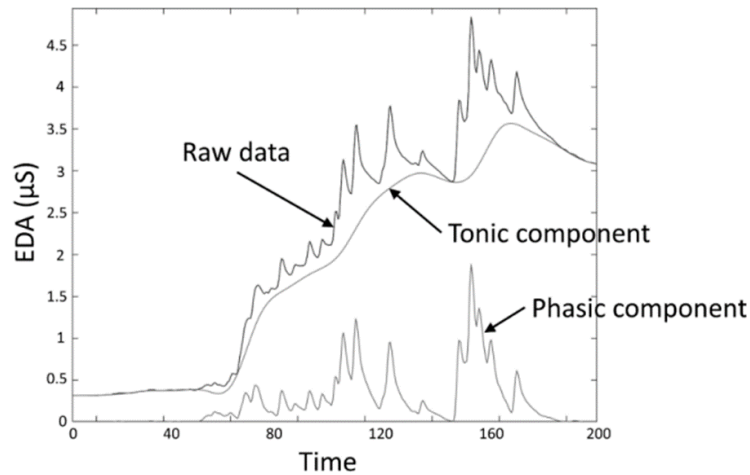


Figure 6: Example of raw EDA signal and its decomposition into tonic and phasic component [39].

## 2.4. Data processing

### 2.4.1. Identification of triggers and signal synchronization

An algorithm was implemented to analyse the video-recording, filmed during the experiment, to recognize the tags, marked directly with the E4 apposite button, and the triggers marked with the flashlight: the video was analysed frame by frame, applying to each of it an image filter; then the tag/trigger was recognized setting a threshold on the pixel intensity and how much of them were present in each frame. This threshold was set empirically after an initial visual inspection of some videos and adopted for all the remaining ones. The corresponding temporal instants, (i.e the instants when the trigger is filmed), were saved as the outcome of this algorithm.

As a last step, the trigger instants were synchronized with respect to the initial tag timestamp.

As already anticipated, the signal acquisition can be affected by motion artefacts, therefore pre-processing algorithm were developed in MATLAB and applied to the signal.

### 2.4.2. BVP filtering

In order to clean the BVP signal from noise and motion artefacts a band pass filter was applied, exploiting accelerometer signals. The cut off frequencies were computed specifically for each patient and for each session in order to have a customized filter.

Starting from the IBI spreadsheet provided by the E4 device, artefacts-free segments of the BVP were identified in an automatic way considering at least 10 consecutive negative peaks. This method was selected since the Empatica device recognizes diastolic peaks only in ideal waveforms [35]. Therefore, the selected segments can definitely be considered as artefacts-free.

The power spectral density (PSD) of both BVP segment and the corresponding acceleration segment were then computed with a fast Fourier transform (FFT) method and then normalized with respect to their maximum amplitude value. Finally, the PSD of acceleration signal was subtracted to the PSD of BVP to identify the motion-free fundamental frequency for each segment. These steps were performed for each artefacts-free segment of the BVP.

Only frequencies belonging to the physiological range of cardiac frequency (1-3 Hz i.e 60-180 bpm) were kept and saved in a new vector.

The maximum (MAX) and minimum (MIN) values of this new vector of fundamental frequencies were then computed and the cut off frequencies for the whole signal were imposed as in Equation(2a), where  $\Delta$  is a safety margin set arbitrarily to 0.1 Hz.

$$f_l = MIN - \Delta \quad (2a)$$

$$f_u = MAX + \Delta \quad (2b)$$

A Butterworth bandpass filter between  $f_l$  and  $f_u$  was finally applied to the BVP signal, from which the new diastolic points were identified and the new inter-beat-intervals were computed as the final outcome of the algorithm implemented.

The main steps of the BVP pre- processing algorithm are summarized below:

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**Algorithm 1:** Pre-processing of BVP signal

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- 1: Artefacts-free BVP segments identification
- 2: **for** each segment found **do**
- 3:     Computation of the power spectral density (PSD) of the BVP segment
- 4:     Computation of the PSD of the corresponding acceleration segment
- 5:     Normalization with respect to the maximum value
- 6:     PSD of BVP segment – PSD of acceleration segment %to find new fundamental frequency ( $ff$ )
- 7:     **if**  $ff < 1\text{Hz}$  or  $ff > 3\text{HZ}$  **then**
- 8:         discard  $ff$  value
- 9:     **else**
- 10:         Save  $ff$  in a new vector of fundamental frequency
- 11:     **end if**
- 12: **end for**
- 13: Maximum and minimum values of the fundamental frequency vector computation
- 14:  $f_l = MIN - 0.1$ ;  $f_u = MAX + 0.1$  %Cut off frequencies of the bandpass filter
- 15: Bandpass filter applied to the BVP signal
- 16: Find negative peaks
- 17: Save new IBI data
- 18: Features extraction

### 2.4.3. BVP feature extraction

From the resulting IBI data, Heart Rate Variability (HRV) parameters (Table 1) were extracted both in the time and frequency domains.

Variable	Description
<b>Time-domain parameters</b>	
mean IBI (ms)	Mean inter-beat interval duration
mean HR (bpm)	Mean heart rate frequency
SDNN (ms)	Standard deviation of all IBI intervals
RMSSD (ms)	Root Mean Square of the Successive Differences
<b>Frequency-domain parameters</b>	
normalized LF (%)	Normalized power in low frequency range (0.04–0.15) Hz
normalized HF (%)	Normalized power in high frequency range (0.15-0.40) Hz
LF norm	Sympathetic modulation index $LF / (\text{Total Power} - \text{VLF})$
HF norm	Vagal modulation index $HF / (\text{Total Power} - \text{VLF})$
LF/HF	Sympato-vagal balance index

Table 1: HRV parameters in the time and frequency domains [34].

### Time-domain parameters

#### Mean IBI

It is the mean value of the temporal difference (in ms) between two consecutive diastolic points. Lower mean IBI values can be associated with a higher stress condition. From this measure, the mean heart rate parameter can be derived as in Equation (3), therefore they are strictly negatively correlated.

$$\text{mean HR} = \frac{60 * 1000}{\text{mean IBI}} [\text{bpm}] \quad (3)$$

#### SDNN

The SDNN is the standard deviation of the inter-beat intervals, measured in milliseconds, which reflects all the cyclic components responsible for variability in the period of recording [40].

When HRV is large and irregular, the SDNN value increases. Therefore, SDNN is an index of physiological resilience against stress [41]. In particular, lower values of SDNN can be associated with higher stress level.

#### RMSSD

The RMSSD is the root mean square of successive differences between normal heartbeats. This value was obtained as shown in the Equation (4):

$$\text{RMSSD} = \sqrt{\sum_{i=1}^{n-1} [\text{IBI}(i+1) - \text{IBI}(i)]^2 / n - 1} [\text{ms}] \quad (4)$$

Where  $n$  is the total number of inter-beat intervals in the BVP signal.

The RMSSD reflects the beat-to-beat variance in heart rate and is the primary time domain measure used to estimate the vagally-mediated changes reflected in HRV [42].

An increase in predictability, regularity, and reduced complexity of the signal (lower RMSSD value) under mental stress condition was reported by [41].

### Frequency-domain parameters

The Task Force report [40] divided heart rhythm oscillations into four primary frequency bands which are High Frequency (HF), the Low Frequency (LF), Very-Low-Frequency (VLF) and Ultra-Low-Frequency (ULF) bands. The ULF band ( $\leq 0.003$  Hz) requires a recording period of at least 24 h [43], therefore it was not included in the present analysis.

#### VLF

The VLF band is the power in the HRV power spectrum range between 0.0033 and 0.04 Hz. Historically, the physiological explanation and mechanisms involved in the generation of the VLF component have not been as well defined as the LF and HF components, for this reason, this region has been largely ignored [42] except for the normalization of the LF and HF index.

#### LF

The LF band ranges between 0.04 and 0.15 Hz. The results of the spectral analysis conducted by [44] showed an increased LF spectral content in mental stress conditions. However, the contribution of the sympathetic system (SNS) and parasympathetic system (PNS) in generating the LF power appears to be unclear with a nonlinear and complex relationship [42].

#### HF

The HF band, which range is [0.15-0.4] Hz, reflects parasympathetic activity. A reduced vagal activity is found in patients under stress, anxiety and worry [41]. For this reason, the normalized power spectrum of the HF component was computed with respect to the total power spectrum to understand the effect of the PNS in the heart rate variability.

## LF/HF ratio

The interpretation of this parameter can be problematic due to the issues related to the LF band already described, in particular for low values where this ratio is often decreased due to reductions in the LF spectral content rather than an increase of the vagal activity. Therefore, a more precise interpretation of the LF/HF ratio should include consideration about HF and LF power.

In contrast, a high LF/HF ratio reflects higher sympathetic activity with respect to the parasympathetic one that can be observed in challenging and stressful situation that requires effort [41,42]. As a matter of fact, the most frequently reported variation in HRV variables associated to psychophysiological stress is a low parasympathetic activity, which is characterized mainly by a decrease in the HF but also by an increase in the LF [41].

## 2.4.4.EDA Pre-processing

The proposed pipeline architecture for EDA signal analysis is shown in Figure 7.

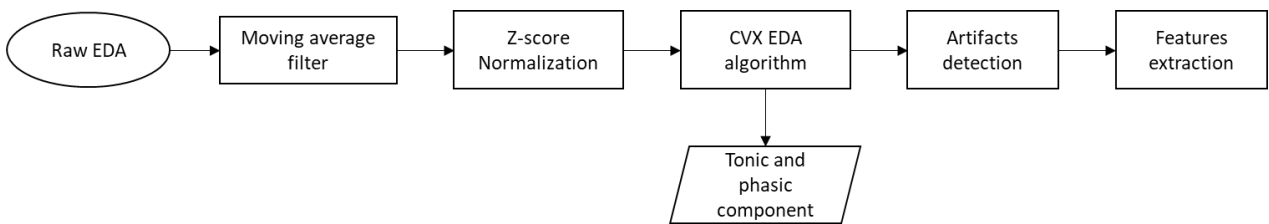


Figure 7: EDA pre-processing scheme.

The decomposition of the EDA signal into tonic and phasic component was performed using a convex optimization method (*cvxEDA algorithm*) implemented by [45]. The proposed model describes the electrodermal activity as the sum of three terms: the phasic component, the tonic component, and an additive white Gaussian noise term, which accounts for measurement and modelling errors. The algorithm requires the user to set two parameters,  $\alpha$  and  $\gamma$ , to penalize respectively the phasic and tonic components of the decomposition: a larger  $\alpha$  reaches a sparser phasic component, while a higher  $\gamma$  produces a smoother tonic component. These values were set according to [22].

Before *cvxEDA* application, a moving average across a 1-second window was applied to smooth the raw signal [46], and as indicated by [45], a z-score normalization was performed in order to standardize the dataset and increase the velocity of the optimization procedure.

If artefacts are present, mainly due to a change in contact or disconnection of the electrodes with the skin, EDA features can be significantly affected, leading to erroneous results, for example in the EDA decomposition process, where an altered tonic and phasic segments may be obtained.

Therefore, it is important to identify, and then remove, those artefacts in order to correctly extract features from the EDA bio-signal:

To address the problem, the stationary Haar wavelet transform was applied, which is an advantageous method for detecting artefacts characterized by sudden changes of the signal, as suggested by [31]. Wavelet coefficients were analysed to recognize sharp changes in the signal applying an adaptive threshold each 1000s-time-window considering as artefacts-related only those coefficients higher than three times their standard deviation in the current time-window.

However, as suggested by [38], even in case of automatic artefact detection and removal techniques, it is advisable to visually inspect the detected artefacts and accept or reject them as artefactual.

Detected artefacts were then removed from the signal and excluded from the feature extraction process and further analysis.



## 2.4.5.EDA feature extraction

From both tonic and phasic components, EDA parameters were extracted both in the time and frequency domains. (Table 2)

Variable	Description
<b>Time-domain parameters</b>	
Mean tonic ( $\mu\text{S}$ )	Mean value of the tonic component
NS.EDRs (#/s)	Frequency of non-specific peaks
Mean amplitude peak ( $\mu\text{S}$ )	Mean of the amplitude of all NS.EDRs in the interval
Std amplitude peak ( $\mu\text{S}$ )	Standard deviation of the amplitude of all NS.EDRs in the interval
Normalized AUC ( $\mu\text{S}$ )	Normalized area under the curve
Mean rise time (s)	Mean temporal distance onset-peak
Mean distance peak-to-peak (s)	Mean distance peak-to-peak
Std distance peak-to-peak (s)	Standard deviation distance peak-to-peak
<b>Frequency-domain parameters [47]</b>	
normalized VLF (%)	Normalized power in very low frequency range [0–0.045] Hz
normalized LF (%)	Normalized power in low frequency range [0.045–0.15] Hz
normalized HF <sub>1</sub> (%)	Normalized power in high frequency range [0.15-0.25] Hz
normalized HF <sub>2</sub> (%)	Normalized power in high frequency range [0.25-0.40] Hz
normalized VHF (%)	Normalized power in very high frequency range [0.4-0.5] Hz

Table 2: EDA parameters in time and frequency domains.

### Time-domain parameters

#### Mean tonic ( $\mu\text{S}$ )

This parameter accounts for the skin conductance level (i.e electrodermal level (EDL) in absence of phasic responses [38]) which is conceived as a measure related to the slow shifts of the EDA related to the general psychophysiological status of the subjects [39].

It was calculated as the mean of the tonic signal, obtained with the *covEDA algorithm*. This parameter is reported to have an increasing trend as effect of sympathetic nervous arousal. [47]

#### Peak-related parameters

NS.EDR (#/s) parameter accounts for the number of non-specific electrodermal responses in the analysed time-period. Non-specific electrodermal responses are spontaneous responses that can not be associated with any specific stimulus. The minimum change in conductance that qualifies a NS.EDR as a response is recommend being between 0.01 and 0.05  $\mu\text{S}$  by [38]. Therefore, according to [37,38,46] the threshold related to the difference between the amplitude of the peak and its corresponding onset was set to 0.015  $\mu\text{S}$ . The onset of a response was determined by stepping back along the phasic EDA curve to the point of maximum curvature, as indicated in [38].

Only the peaks of the phasic data that were above this threshold were then assumed as NS.EDRs. If a second response (with amplitude over the set threshold) occurred before the completion of a previous one (i.e two responses overlapped), they were both considered as effective peaks [38].

This parameter is a measure of the NS.EDR-frequency (peaks per seconds): the total number of NS.EDR found was then normalized with respect to the duration of the artefacts-free EDA segment considered.

Moreover, the distance peak-to-peak parameter, and its standard deviation, were calculated as additional information related to the response frequency.

An increased frequency response is reported as index of increased sympathetic nervous arousal. [38]

Mean peaks amplitude, relative standard deviation and Area Under the Curve (AUC) parameters were then computed as indices of the magnitude of the response, considering only the effective spontaneous responses. More in detail, higher amplitude can be associated with higher sympathetic response. Finally, the rise time was computed as the time difference from the occurrence of the peak response and its onset. Analysis on rise time parameter should be conducted also considering the amplitude of the responses. In particular, given the same amplitude, a reduced rise time may indicate a faster response, and thus greater arousal.

### *Frequency domain parameters*

As for HRV frequency parameters, the spectral content of the EDA signal is typically divided into four primary frequency bands which are the Very-Low-Frequency (VLF- [0–0.045] Hz), Low Frequency (LF- [0.045–0.15] Hz), High Frequency (HF- [0.15-0.40] Hz) and Very-High-Frequency (VHF- [0.40-0.50] Hz) bands.

Spectral content of these frequency bands were normalized with respect to the EDA total power.

As reported by [47], at rest, the spectral content of the EDA signal more sensitive to central sympathetic control is confined to the frequencies in the [0 - 0.25] Hz range with a very small amount of spectral power present outside this range. For this reason, the HF frequency band was divided in the HF<sub>1</sub> ([0.15-0.25] Hz) and HF<sub>2</sub> ([0.25-0.40]) bands, to better evaluate the sympathetic modulation on the electrodermal activity.

At well-being conditions, the greater power is found in the VLF band, while an increased spectral content of the [0.045-0.5] Hz range (i.e from LF to VHF frequency bands), is typically found in response to increased mental workload, as confirmed by [48–50], with a resulting decrease of the VLF spectral power.

## 2.5. Processing of self-evaluation and therapist's evaluation questionnaires

VAS questionnaires were proposed to the subjects during the pre-Lokomat and post-Lokomat phase, in order to collect patients' self-evaluation about their emotional state before and after the treatment.

In both self-evaluation questionnaires, the following questions were proposed:

- Q1. "Are you worried?"
- Q2. "Are you happy"
- Q3. "Are you sad?"
- Q4. "Are you angry?"
- Q5. "Are you scared?"
- Q6. "Are you bored?"

Possible answers were: not at all, a little, very much.

During rehabilitation treatment, the physiotherapist was asked to fill in an *ad hoc* questionnaire to collect a reliable evaluation of different levels of anxiety, activity, persistence of the patient. In particular, items of the proposed therapists' evaluation are reported below:

- Q1. "The patient is passive/ proactive"
- Q2. "The patient is fearful/in control of the situation"
- Q3. "The patient is anxious/relaxed"
- Q4. "The patient is impulsive /thoughtful"
- Q5. "The patient is distracted /focused"
- Q6. "The patient is hyperactive/quiet"
- Q7. "The patient underestimates/overestimates his/her abilities"
- Q8. "The patient is not/ is persistent"
- Q9. "The patient is concerned/does not care about failure"
- Q10. "The patient is unable/able to derive satisfaction from success"
- Q11. "The patient manages emotions in a negative/positive manner"
- Q12. "The patient does not/does actively seek information to learn and update"

The therapist gave an evaluation to each item with a numerical score ranging from -3 to 3, where the lowest value is associated with negative emotional state, while the maximum score is related to maximal well-being condition.

For statistical analysis, responses from both self-evaluation questionnaires were converted into a numerical score from 1 to 3, while the therapist's evaluations were converted from 0 to 6.

In addition, for each item of the self-evaluation and therapist' evaluation the median and interquartile values of the responses were computed.

Drawing-like questionnaires were evaluated only qualitatively, to understand patients' emotional state towards Lokomat itself, the therapy, games, and general patients' experience during the active training.

## 2.6. Statistical analysis

HRV and EDA features (Table 1 and Table 2) were extracted for different time-periods:

- Pre-Lokomat questionnaire
- Lokomat exercises
- Post-Lokomat questionnaire

Firstly, to identify parameters that might be indicative of the subject's emotional state (second objective of the present study), correlation between HRV/EDA features, acquired during the Lokomat exercises, and all the questionnaires responses (self-evaluation and therapists' evaluation) were performed evaluating the Kendall's  $\tau$  coefficient.

Moreover, to assess the patient's emotional state in the first recorded session and to understand whether any changes from the first to the second session were present (third objective), differences between the first and last session of Lokomat were investigated, analysing both the HRV/EDA parameters and the self-evaluation and therapist's evaluation questionnaires responses.

Data normality was verified with the Kolmogorov-Smirnov test.

First, a Friedman test was used to assess potential differences in terms of VAS *ad hoc* questionnaire answer among 4 timepoints (pre/post of the two sessions). Then, a Wilcoxon test was used to look for potential differences in terms of therapist's evaluation.

As for Lokomat parameters, before any statistical analysis, data normalization was performed subtracting the data collected during the last phase of the recording (after the conclusion of the active Lokomat training). As a matter of fact, this was the most reliable phase, as signal stabilization, which requires few minutes, was guaranteed; furthermore, the subject was still and quiet.

## 3. Results

During the present work, 16 subjects were recruited. These subjects (9 male and 7 female), ranging in age from 6 to 23 years old ( $10.06 \pm 5.31$ ; mean  $\pm$  SD) suffered from cerebral palsy, acquired brain injury or hereditary spastic paraplegia.

### 3.1. Implementation of signal processing algorithms

With respect to the first objective, signal synchronization was initially performed: the triggers collected during the session were initially synchronized with the signal recorded by the E4 wristband (Figure 8). This method allowed to recognize different parts of the rehabilitation session in each analysed signal.

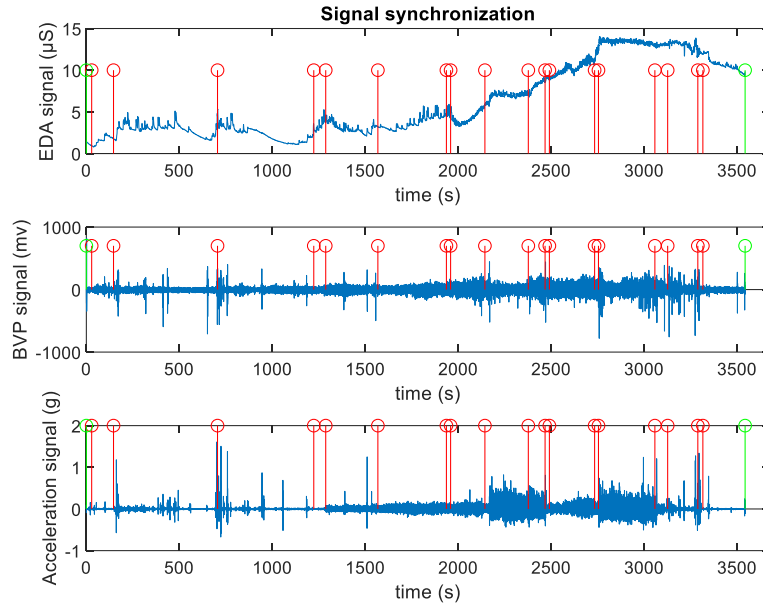
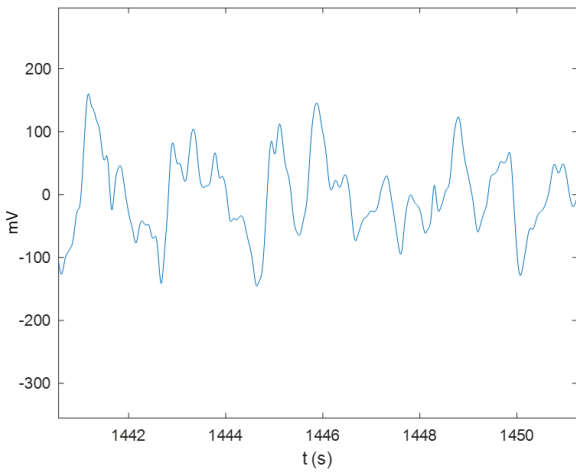


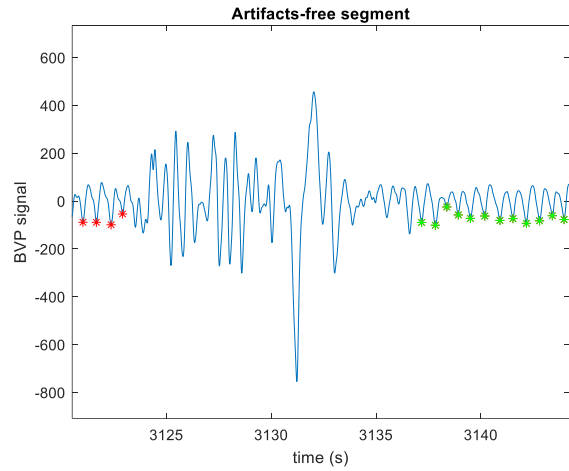
Figure 8: EDA, BVP and acceleration signal synchronization. Initial and final tags (green) and during-session triggers (red).

The extracted signals were then processed with algorithms implemented during the present work, for motion artefacts removal and feature extraction.

The Figure 9a shows an example of the raw BVP signal extracted by E4 wristband: it can be seen that the comparison with the expected signal (Figure 5) highlights the presence of motion artefacts corrupting the obtained signal.



(9a) Example of BVP raw signal, subject 2 session 2.



(9b) Example of artifacts-free segments identification. Subject UX03, session 2.

Figure 9: Examples of extracted BVP signal.

For this reason, a band pass filter was applied to the signal, as described in the section 2.4.2, starting from the identification of artefacts-free portions of the signal, which was performed using the diastolic peaks detected by the device in real time (Figure 9b).

Figure 10 shows how the raw BVP signal was successfully filtered and recovered, as a result of the algorithm implemented during the present work.

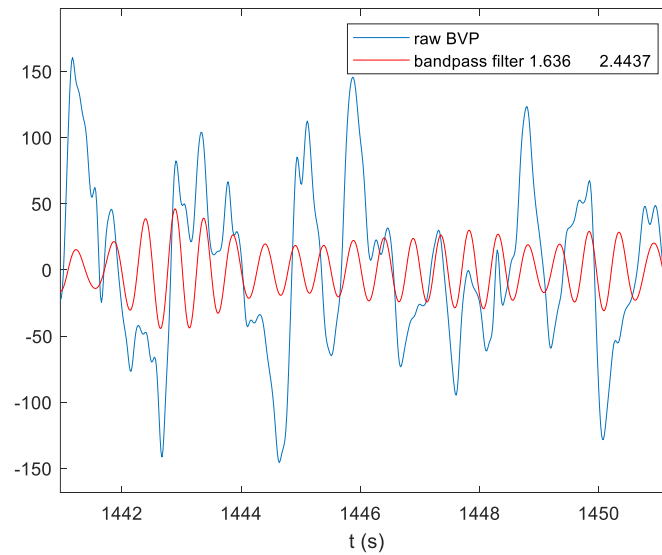


Figure 10: Raw (blue) and filtered (red) BVP signal of subject 2 session 2.

On the other hand, EDA decomposition signal into tonic and phasic components (Figure 11) was performed using the *cvxEDA* algorithm implemented by [45].

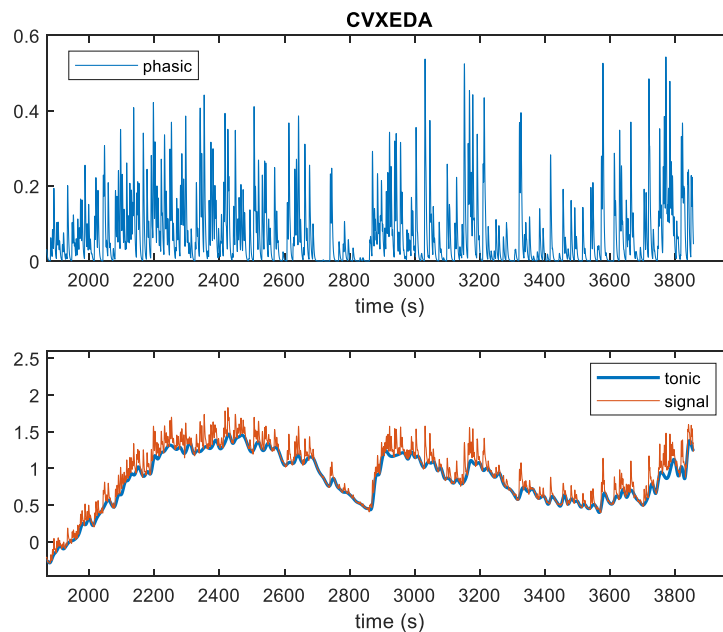


Figure 11: Outcome of the *cvxEDA* algorithm: decomposition into phasic and tonic component. Subject 8 session 2.

Moreover, artefacts detection was performed with a stationary wavelet transform, as previously explained. From Figure 12, it can be seen that artefacts were correctly identified.

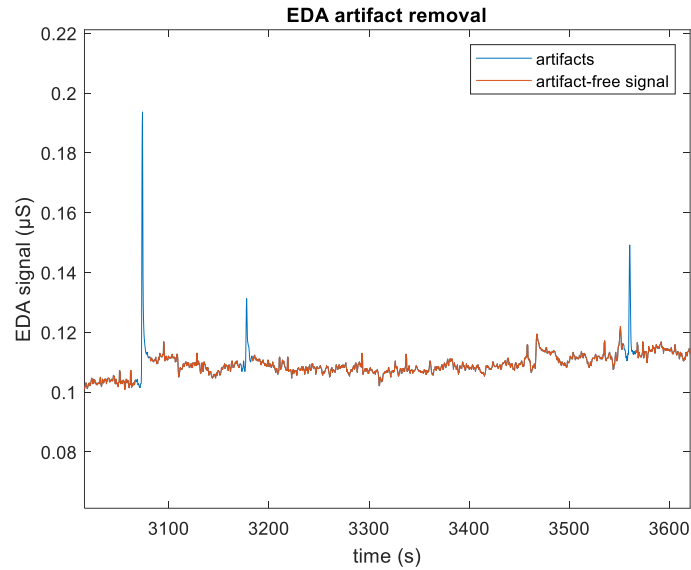


Figure 12: Artefacts identification and removal: in orange the artefact-free signal; in blue artefacts segment.

### 3.2. Self-evaluation and therapist's evaluation questionnaires responses

From questionnaires responses, it was clear (Figure 13) that a feeling of happiness prevailed in patients during both the previous and post-Lokomat phases. In addition, therapist's evaluation reported a generalized patients' well-being condition.

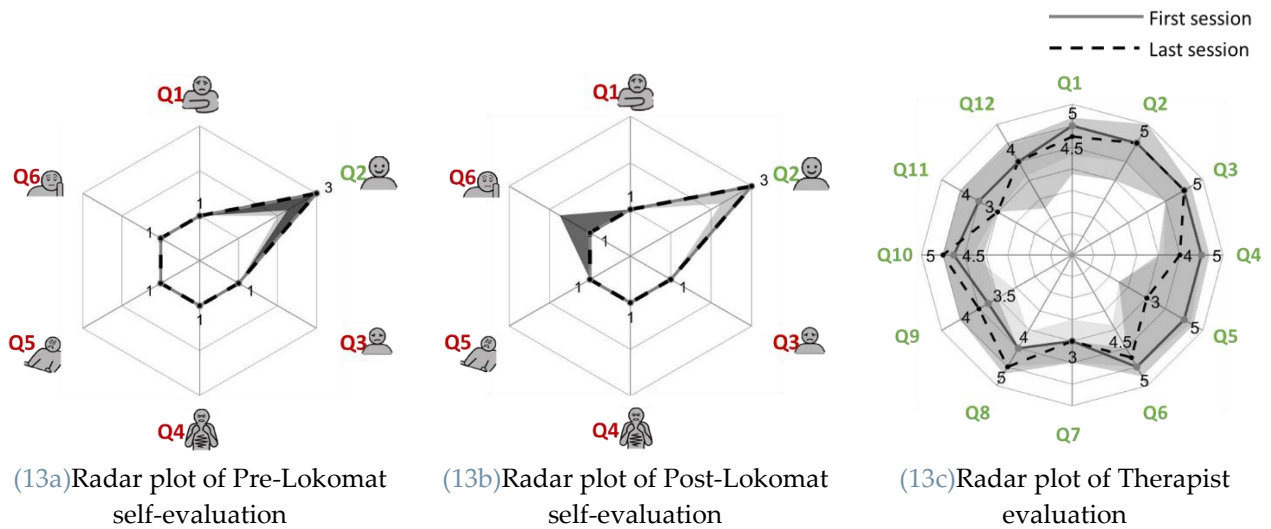


Figure 13: Radar plot of questionnaires responses. Labels  $Q_1 - Q_n$  were assigned as in section 2.5. The continuous line represents median values of the first session, while the dotted line accounts for the second session. Interquartile ranges are shown with the grey area: the brighter area is related to the first session while the darker area is related to the second session.

The drawing-like questionnaires showed that patients had a positive attitude towards the therapy and the Lokomat, indeed Lokomat games and exercises were described as fun and enjoyable. In addition, they believe that they will be able to walk better in the future thanks to this rehabilitation therapy.



### 3.3. Identification of parameters able to detect a negative/positive emotional state

Only a moderate correlation was found between the HRV/EDA parameters, recorded during the Lokomat-treatment phase, and the questionnaire answers, and between these parameters and therapists' evaluation (Table 3, Table 4, Table 5).

Interestingly, only EDA frequency parameters resulted to be correlated with both emotion-related patients' responses (related to feelings of sadness-Q3 and worry-Q1) and therapists' evaluations (particularly those about emotion handling -Q11 item). In details, VLF was positively correlated to positive emotional state while the other frequency bands to negative emotional states.

In addition, [51] reported that these features can provide more consistent results when compared to time domain parameters and HRV features. For these reasons, the EDA frequency parameters were considered as the most informative.

	Q1	Q2	Q3	Q4	Q5	Q6
Mean IBI	-0.05	0.20	-0.13	-0.08	-0.07	0.08
RMSSD	-0.27	0.03	-0.05	-0.11	-0.16	-0.16
SDNN	-0.24	0.13	-0.13	-0.12	-0.17	-0.10
Mean HR	0.02	-0.20	0.12	0.09	0.05	-0.09
normalized LF spectrum	-0.21	-0.02	0.00	-0.16	-0.06	-0.03
normalized HF spectrum	-0.18	0.02	-0.11	-0.15	-0.10	-0.35
Sympathetic modulation index	0.07	0.06	0.09	0.05	0.11	0.30
Vagal modulation index	-0.07	-0.06	-0.09	-0.05	-0.11	-0.30
Sympatovagal balance index	0.07	0.06	0.09	0.05	0.11	0.30
Mean tonic	0.20	0.14	-0.01	0.21	0.06	0.12
NS.EDRs (#/s)	0.15	-0.18	0.27	0.08	0	0.01
Mean amplitude peak	0.12	-0.05	0.06	0.12	0.04	0.19
std amplitude peak	0.07	0	0.02	0.09	0.08	0.19
normalized AUC	0.22	-0.08	0.19	0.16	0.03	0.16
Mean rise time	-0.19	0.05	0.04	-0.09	0.14	-0.03
Mean distance peak-to-peak	-0.16	0.16	-0.20	-0.17	-0.03	-0.03
std distance peak-to-peak	-0.15	0.05	-0.25	-0.16	-0.08	-0.01
VLF	-0.07	0.10	-0.28	0.03	-0.02	-0.03
LF	0.07	-0.07	0.26	-0.03	0.05	0.03
HF <sub>1</sub>	0.06	-0.13	0.27	-0.01	0	0.02
HF <sub>2</sub>	0.07	-0.18	0.35	-0.05	0.01	0.05
VHF	-0.01	-0.25	0.34	-0.14	-0.01	-0.03

Table 3: Kendall's  $\tau$  coefficients between HRV/EDA parameters and Pre-Lokomat self-evaluation responses. Significant correlations are highlighted: darker the colour, higher the correlation.

	Q1	Q2	Q3	Q4	Q5	Q6
Mean IBI	0.04	-0.02	-0.05	-0.06	-0.04	0.08
RMSSD	0.03	-0.05	-0.12	-0.19	0.13	0.08
SDNN	0.06	-0.08	-0.08	-0.19	0.11	0.12
Mean HR	-0.03	0.01	0.05	0.06	0.06	-0.08
normalized LF spectrum	-0.25	0	-0.12	-0.11	-0.14	-0.13
normalized HF spectrum	-0.16	0.18	-0.21	-0.19	0.02	-0.12
Sympathetic modulation index	0.01	-0.08	0.16	0.16	-0.14	0.05
Vagal modulation index	-0.01	0.08	-0.16	-0.16	0.14	-0.05
Sympatovagal balance index	0.01	-0.08	0.16	0.16	-0.14	0.05
Mean tonic	-0.04	0.25	0.19	0.20	0.13	0.08
NS.EDRs (#/s)	0.11	0.14	0.05	0.07	0.15	-0.03
Mean amplitude peak	0.23	0.08	-0.03	0.06	0.21	0.28
std amplitude peak	0.21	-0.02	-0.06	0.04	0.16	0.32
normalized AUC	0.25	0.18	0	0.08	0.26	0.19
Mean rise time	-0.10	-0.04	-0.21	-0.07	-0.06	0.01
Mean distance peak-to-peak	-0.08	-0.11	-0.16	-0.18	-0.15	0.00
std distance peak-to-peak	-0.06	-0.13	-0.16	-0.20	-0.12	-0.01
VLF	-0.28	0.01	0.08	0.07	-0.13	-0.06
LF	0.27	0.01	-0.07	-0.07	0.12	0.09
HF <sub>1</sub>	0.29	-0.01	-0.08	-0.06	0.16	0.07
HF <sub>2</sub>	0.30	-0.08	-0.05	-0.10	0.13	0.01
VHF	0.23	-0.16	-0.05	-0.15	0.01	-0.11

Table 4: Kendall's  $\tau$  coefficients between HRV/EDA parameters and Post-Lokomat self-evaluation responses. Significant correlations are highlighted: darker the colour, higher the correlation.

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Mean IBI	-0.09	-0.14	-0.10	-0.01	-0.10	-0.06	-0.04	-0.19	0.07	0	0.04	-0.22
RMSSD	-0.09	0.01	-0.14	-0.01	0.12	0.10	-0.04	-0.01	0.12	-0.04	0	0.15
SDNN	-0.08	-0.05	-0.16	-0.03	0.06	0.05	-0.08	-0.08	0.12	-0.07	0.02	0.07
Mean HR	0.08	0.13	0.10	0.02	0.12	0.08	0.05	0.21	-0.05	-0.01	-0.02	0.22
normalized LF spectrum	-0.01	-0.07	-0.02	-0.14	-0.17	-0.01	0.01	-0.04	0.00	-0.04	0.02	-0.08
normalized HF spectrum	-0.06	0.04	0.00	-0.03	0.05	0.13	0.03	-0.02	0.10	-0.02	-0.09	0.14
Sympathetic modulation index	0.10	-0.02	0.02	-0.04	-0.13	-0.15	-0.04	-0.02	-0.06	0.07	0.12	-0.14
Vagal modulation index	-0.10	0.02	-0.02	0.04	0.13	0.15	0.04	0.02	0.06	-0.07	-0.12	0.14
Sympatovagal balance index	0.10	-0.02	0.02	-0.04	-0.13	-0.15	-0.04	-0.02	-0.06	0.07	0.12	-0.14
Mean tonic	0.11	-0.09	-0.06	-0.18	-0.06	-0.16	-0.07	0.08	-0.04	-0.07	0.06	0.14
NS.EDRs (#/s)	0.11	0.15	0.01	-0.09	0.02	-0.07	-0.12	0.12	0.01	-0.05	-0.07	0.04
Mean amplitude peak	0.11	0.06	0.01	-0.05	-0.04	0.02	-0.22	0.02	-0.16	0.09	-0.12	-0.11
std amplitude peak	0.06	0.04	-0.05	-0.05	-0.07	-0.03	-0.22	-0.02	-0.14	0.09	-0.05	-0.10
normalized AUC	0.11	0.09	-0.01	-0.13	-0.06	-0.05	-0.23	0.04	-0.15	0.08	-0.17	-0.07
Mean rise time	-0.11	-0.01	-0.01	-0.01	-0.01	-0.01	0.05	-0.06	0.03	0.09	0.16	0.05
Mean distance peak-to-peak	-0.19	-0.22	-0.07	0.03	-0.10	0.01	0.11	-0.19	-0.08	0.02	-0.01	-0.11
std distance peak-to-peak	-0.14	-0.17	-0.01	0.08	-0.07	0.06	0.12	-0.12	-0.06	0.02	-0.07	-0.18
VLF	0.06	-0.07	0.11	0.02	0.04	-0.01	0.19	0.12	0.08	0	0.23	0.18
LF	-0.05	0.07	-0.10	-0.01	-0.04	0.02	-0.19	-0.14	-0.06	0	-0.23	-0.20
HF <sub>1</sub>	-0.04	0.08	-0.10	-0.04	-0.04	-0.03	-0.22	-0.10	-0.09	-0.01	-0.23	-0.17
HF <sub>2</sub>	-0.06	0.10	-0.10	0	0.02	0.02	-0.17	-0.09	-0.06	-0.01	-0.26	-0.17
VHF	-0.05	0.12	-0.09	0.05	0.10	0.05	-0.03	-0.04	-0.01	-0.07	-0.26	-0.09

Table 5: Kendall's  $\tau$  coefficient between HRV/EDA parameters and therapists' evaluation. Significant correlations are highlighted.

### 3.4. Potential changes in emotional wellbeing during Lokomat rehabilitation

Figure 13a and Figure 13b show the median values of the scores for the pre and post questionnaire in the two sessions.

The Friedman test, performed to assess potential differences in terms self-evaluation responses, did not reveal any statistically significant differences among the four time-points (for all responses  $p > 0.194$ ).

In addition, no significant differences were identified for therapist's evaluation responses between the first and last session (for all responses  $p > 0.05$ , Figure 13c).

Finally, comparing the normalized data of the first and last Lokomat-treatment phases, no significant differences were identified by the statistical test (for all parameters  $p > 0.05$ ). Interestingly, VLF spectral contents were higher than other frequency bands during both Lokomat sessions (Figure 14).

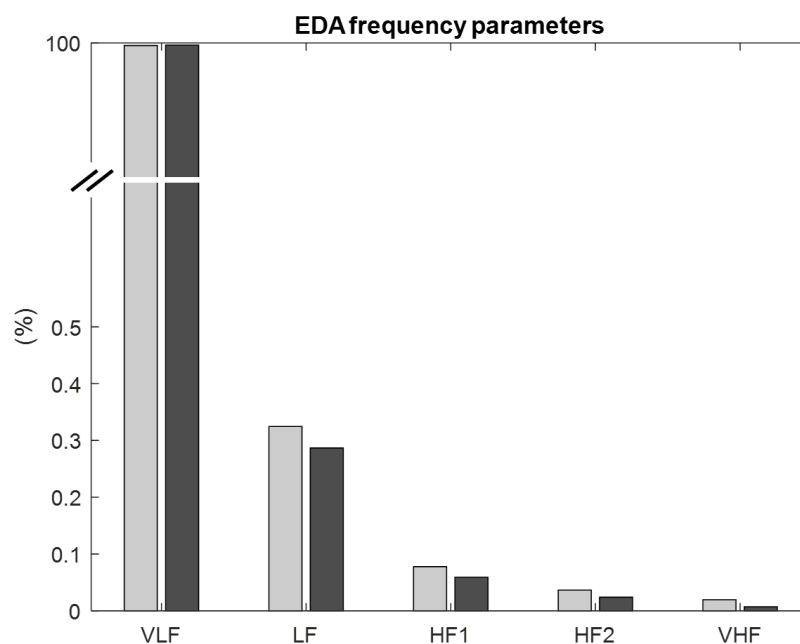


Figure 14: VLF, LF, HF<sub>1</sub>, HF<sub>2</sub>, VHF spectral contents in the two sessions (gray first session, black second session).

## 4. Discussion

The present analysis aimed to monitor the patient's emotional condition during the rehabilitation activity, in the preceding and following phases, investigating whether any differences between sessions were present.

To this end, both quantitative and qualitative data were collected: responses from questionnaires suggested that walking with the Lokomat system was perceived as a positive experience by the subjects, who mostly expressed a feeling of happiness. In addition, examining the drawing-like questionnaires, games and exercises were mostly described as fun and enjoyable and a feeling of hope towards the effects and the success of the therapy were expressed.

The results obtained from the correlation studies showed a moderate correlation between EDA frequency parameters and questionnaires responses related to negative feelings (such as sadness or worry) but also between these features and therapists' evaluation related to the ability to manage emotions.

More in detail, it can be seen that the VLF spectral content increased as the positive emotional state increased, therefore the subject was more able to manage emotions, (i.e. higher score obtained in the checklist evaluation). The same trend was found in the relationship between data and self-evaluation questionnaire responses: the less sad (or worried) the subject was, the more the spectral content in the range [0–0.045] Hz increased. This increasing trend can be explained as a decrease in the phasic response due to a lower mental stress condition, as confirmed by [48–50].

However, despite significant  $p$ -values, the Kendall's  $\tau$  coefficients showed moderate correlations in both cases. The reason for this may be a small sample size: so far, only 16 subjects' data were studied, while the experimental protocol planned a sample size of 40 subjects at the end of the research, leading to more robust correlation results.

EDA parameters can thus be considered as the most indicative of a patients' positive/negative emotional state, as also suggested by [51], who reported that these features can provide more consistent results when compared to time domain parameters and HRV features.

Normalized Lokomat-data were compared among different sessions and no significant differences were identified, supporting the assumption that Lokomat rehabilitation did not alter the emotional state of the subjects. This was confirmed also by self-evaluation and therapist's evaluation responses, that did not change with statistical significance between the first and last session.

## 5. Conclusions

The present thesis project arises from the necessity to explore patients' emotional state during rehabilitation sessions. Most traditional approaches investigate the effectiveness of therapy focusing mainly on the technical aspects, ignoring patients' psychophysiological state, which can greatly contribute to the final outcome of the therapy [14].

Patients who were prescribed with Lokomat-rehabilitation therapy were enrolled in the study, in which BVP and EDA bio-signals were collected with the E4 wristband device (Empatica®, Milan, Italy) during rehabilitation and questionnaire-filling phases.

The bio-signals of interest were processed with algorithms implemented during the present work, in order to filter these data from motion artifacts and to extract key parameters, used to investigate emotional states (positive or negative) in participants.

Self-evaluation responses and therapists' evaluation suggested that Lokomat-therapy appeared to induce no particular state of stress or anxiety. This was also confirmed by statistical analysis of the bio-signals between sessions, which showed no significant variations in the subjects' emotional state during the rehabilitation treatment.

Any changes could be detected by analyzing EDA frequency parameters that correlated, even if moderately, with self-evaluation responses (*'are you sad?'*, *'are you worried?'*) and therapists' evaluation (item related to ability of dealing with emotions).

Nevertheless, the study has some limitations. The first one is related to the signal processing, that was not fully automated and a visual inspection was often necessary. Future developments should, therefore, focus on total automation of these tools for possible real-time data extraction and analysis.

Another point to highlight is the small sample size: as already emphasized, only 16 participants were included and enrolled during the present work, while at the end of the research a sample size of 40 subjects is estimated, leading to more robust results.

Lastly, some modifications should be introduced to the experimental protocol, although the complexity of not interfering with the rehabilitation treatment is recognized.

It is suggested to introduce a baseline walking period during the Lokomat rehabilitation phase, in order to have a non-stressed reference condition, reduce differences due to physical effort and ensure data consistency. Moreover, it might be useful to determine, with the help of physiotherapist, which game challenged the patient the most during rehabilitation, so that it could be taken as a stress-level.

Nevertheless, from preliminary results that emerged from the present work, it can be concluded that it is possible to investigate the subjects' emotional state during the rehabilitation session through the bio-signals recorded by the E4 wristband.

Future developments may lead to automatically identify stressful situation during the rehabilitation session, allowing the therapy adjustment based not only on physical performance but also on psychological condition, in order to maximize the rehabilitation outcome.

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## 7. Abstract in lingua italiana

La riabilitazione robotica assistita è un intervento ormai consolidato per la riabilitazione del cammino dei pazienti con patologie neuromotorie. Tuttavia l'aspetto motorio deve essere integrato con valutazioni sullo stato psicologico del soggetto, fattore determinante per il completo successo della terapia.

Scopo del presente lavoro di tesi è valutare la condizione psicofisica di 16 pazienti che affrontano un percorso riabilitativo con il sistema Lokomat presso IRCCS Medea, utilizzando sia valutazioni riportate dagli stessi e dal loro terapeuta che biosegnali relativi all'attività elettrodermica(EDA) ed alla frequenza cardiaca(BVP), raccolti con il braccialetto sensorizzato E4 e processati con algoritmi implementati durante il progetto di tesi. Ulteriore obiettivo è verificare se vi siano parametri estratti dai dati fisiologici che correlano con quanto riportato nelle valutazioni raccolte, tali da identificare indicatori dello stato emotivo.

Sono quindi stati implementati algoritmi per l'elaborazione dei segnali e la rimozione da artefatti da movimento. Il segnale BVP è stato filtrato sfruttando la registrazione dall'accelerometro del dispositivo, mentre per il segnale EDA è stata utilizzata una trasformata wavelet stazionaria. Per entrambi i segnali sono stati estratti parametri nel dominio del tempo e delle frequenze.

L'analisi di correlazione tra parametri biologici e le valutazioni di pazienti e terapisti ha mostrato che i parametri in frequenza dell'EDA sono i più indicativi per la valutazione dello stato emotivo del soggetto. L'analisi statistica dei dati acquisiti, confrontati tra la prima e ultima seduta, evidenzia che i soggetti affrontano positivamente la terapia conservando tale stato per tutto il trattamento.

Sulla base di tali risultati preliminari si può concludere che sia possibile indagare lo stato emotivo dei soggetti mediante registrazione di segnali fisiologici con dispositivo E4.

Sviluppi futuri prevedono modifiche al protocollo tali da rilevare automaticamente eventuali fasi del trattamento in cui il paziente si mostri più stressato, per adattare la terapia allo stato emotivo dello stesso.

**Parole chiave:** Lokomat, empatica E4, segnale BVP, segnale EDA, valutazione stato emotivo