



Enhanced External Counterpulsation (EECP) Therapy System Supported by Synchronous Vital Monitoring

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Abstract— Coronary artery diseases rank among the leading causes of mortality worldwide and in Türkiye. According to OECD data, our country is unfortunately not in a favorable position in terms of early diagnosis rates and timely access to treatment planning. The therapeutic approach is based on the principle of dilating coronary vessels and their fine terminal branches, while promoting the development of collateral circulation networks between these branches. This ensures adequate myocardial perfusion in patients with vascular occlusion or stenosis, thereby preventing symptoms such as chest pain, fatigue, shortness of breath, or palpitations. Furthermore, it reduces the risk of myocardial infarction and significantly improves patient quality of life.

In this study, the design process of a medical device capable of monitoring vascular obstructions through a non-surgical approach and contributing to early treatment was described using scientific methodology. Instead of a dual-compressor configuration, a compressor–vacuum combination was employed to ensure mechanical continuity, resulting in a linear pressure system operating between 0–5 bar. In the pneumatic design, transmission losses were minimized through leak tests to ensure tight sealing. Additionally, single-lead ECG recording, pulse rate detection, and ST-segment duration measurements were integrated to achieve synchronized operation with EECP therapy.

The developed electronic and pneumatic modules were enclosed in a dedicated housing, making the system ready for clinical research. Performance evaluation was conducted by validating pressure stability, leak integrity, and vital parameter signals using reference measurement devices. In all tests, results were within a $\pm 5\%$ tolerance range.

Keywords—Enhanced External Counterpulsation, Cardiovascular Medical Devices, Pneumatic System Design, Real-Time Physiological Monitoring

I. INTRODUCTION

Cardiovascular diseases (CVDs) remain the leading cause of morbidity and mortality worldwide, with coronary artery disease (CAD) accounting for a substantial proportion of cases [1]. Enhanced External Counterpulsation (EECP) is a non-invasive, U.S. Food and Drug Administration (FDA)-approved therapy for patients with refractory angina and CAD who are not candidates for invasive revascularization [2]. The therapy operates by cyclically inflating and deflating pneumatic cuffs positioned around the patient's lower extremities, synchronized with the cardiac cycle via electrocardiogram (ECG) signals [2], [3].

Inflation during diastole augments coronary perfusion pressure, enhances venous return, and promotes collateral vessel formation through shear stress-mediated arteria genesis [4–6].

Multiple clinical studies and meta-analyses have demonstrated the efficacy of EECP in improving angina symptoms, left ventricular systolic function, myocardial perfusion, and overall quality of life [1, 7, 8]. Data from Türkiye further indicate that EECP provides sustained reductions in angina frequency, improves New York Heart Association (NYHA) functional class, and enhances left ventricular ejection fraction in local patient populations [9, 10]. Recent evidence also suggests that EECP may improve endothelial function, microcirculatory health, exercise tolerance, and metabolic capacity [8, 11]. Biochemical studies have reported favorable modulation of circulating markers, including nitric oxide, endothelin-1, and high-sensitivity C-reactive protein following treatment [11]. The precision and safety of EECP depend on accurate synchronization with the cardiac cycle and stable pneumatic pressure control. Integrating synchronous vital monitoring—comprising single-lead ECG, pulse rate detection, and ST-segment duration measurement—into EECP systems may not only improve therapeutic outcomes but also facilitate early diagnosis and real-time safety monitoring, which is particularly relevant in regions such as Türkiye where the cardiovascular disease burden is high.

This study presents the design and integration of an EECP system incorporating synchronous vital sign monitoring, optimized for clinical readiness in Türkiye. The device employs a compressor–vacuum pneumatic configuration operating in the 0–5 bar range to ensure linear pressure delivery and mechanical continuity, with leak-tested sealing to minimize transmission losses. A microcontroller-based control unit (Arduino Mega) with relay-actuated valves provides precise timing and coordination for pneumatic operation, synchronized with ECG, pulse rate, and ST-segment measurements. All pneumatic and electronic modules are housed in custom enclosures, with dedicated valve boxes to ensure mechanical stability, vibration reduction, and component protection. Power is supplied through a transformer converting 220 V AC to 24 V DC, enabling safe and stable distribution to all subsystems. The mechanical, electrical, and pneumatic assemblies are integrated into a single, unified structure with organized tubing and wiring to ensure durability, accessibility, and ease of maintenance.

The study describes the mechanical, pneumatic, and electronic design of an EECF system triggered by electrocardiogram (ECG) signals acquired from a vital parameter monitor developed by our research group. The work reports on technology readiness level (TRL) 8 developments completed prior to initiating the clinical research phase.

II. MATERIALS AND METHODS

The system was assembled from pneumatic components, control electronics, power supply modules, and structural supports. A microcontroller-based unit governed relay-actuated valves powered through a stepped-down electrical source. Pneumatic conduits were routed and secured to the main frame, and custom enclosures were fabricated for structural stability and component protection. Final integration included mechanical mounting, electrical interconnection, and pneumatic coupling to yield a fully functional prototype.

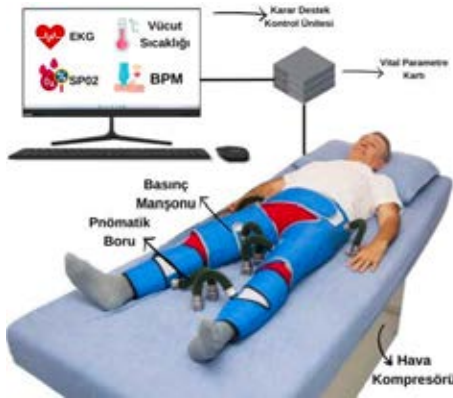


Figure 1. Compact View of EECF System

A. Air Supply Unit

The air supply unit delivers the pressurized and vacuum air required for system operation. It comprises an oil-free compressor to generate clean compressed air and a vacuum pump to produce the necessary negative pressure. These components constitute the core of the pneumatic subsystem, providing consistent and reliable airflow to sustain device functionality.



Figure 2. PROTER Air Compressor / VALUE VE-115 Vacuum Pump and Power Connections

B. Power Supply and Distribution

The power supply and distribution subsystem convert mains electricity to the operating voltages required by the control and

actuation components. It incorporates a transformer unit and associated wiring to deliver stable power to the electronic circuits and pneumatic controls, while ensuring safe and organized electrical distribution throughout the device.

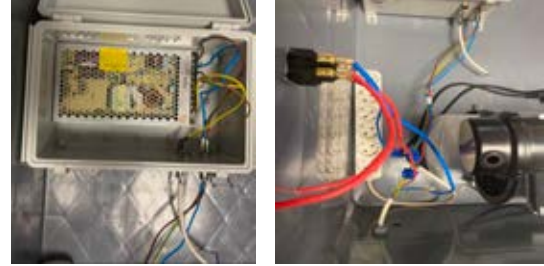


Figure 3. Input 220v, Output 24v Power Connection Box

C. Control and Vital Parameter Circuits

The control unit regulates pneumatic system operation by processing input signals and generating actuator commands. It is based on a microcontroller platform interfaced with relay modules that switch pneumatic valves on and off as required. This configuration enables precise timing and synchronized control of device functions. The PM4100, as an OEM board, can interface with any microprocessor or microcontroller. This compatibility requires serial communication between the OEM board and the host microprocessor/microcontroller. The serial link is configured as UART at 115200 bps, with 8 data bits, 1 stop bit, and no parity. Figure 4 presents the design of the slave Arduino boards used to control the relay modules in conjunction with the vital parameter monitor.



Figure 4. Arduino MEGA with 8xRelay Module and PM-4100 Vital Parameter Circuit

D. Pneumatic Components

The Pneumatic Components form the functional core of the air-driven system, consisting of valves, tubing, and connectors that direct and control airflow. The valves regulate the timing and sequence of air delivery, while the tubing and fittings ensure secure and efficient transfer of pressurized or vacuum air between system elements.



Figure 5. Pipes and Connectors

Actuators

The Valve Actuation and Housing system controls the airflow through precision pneumatic valves, which are responsible for executing the device's operational cycles. These valves are securely mounted within custom-designed protective boxes to ensure stability, minimize vibration, and protect the components from environmental factors. The enclosures also facilitate organized routing of pneumatic lines and wiring, contributing to the overall durability and maintainability of the system renders.

The final system assembly integrated all mechanical, pneumatic, and electrical subsystems into a fully operational unit. Following the preparation of the air supply, power distribution, control, and valve actuation subsystems, each was mounted in its designated location within the device frame. Pneumatic lines were routed through pre-drilled passages to provide secure, unobstructed connections to the end-use components, while electrical wiring was organized to ensure accessibility and operational safety. Valve boxes were installed to protect and stabilize the actuation components, preventing displacement during operation. All air and electrical connections were tested for continuity and leakage to verify system integrity.

III. RESULTS AND DISCUSSION

R peaks were detected from the QRS complex by thresholding peaks exceeding 0.5 mV (MinPeakHeight = 0.5) and enforcing a minimum inter-peak interval of 200 samples (MinPeakDistance = 200) to suppress false detections. Q-wave localization was performed after noise reduction using a Savitzky–Golay filter. Peaks within the −0.2 mV to −0.5 mV amplitude range were classified as Q waves.

Subsequently, the positions of the Q waves were determined. Direct peak thresholding for Q-wave detection is prone to errors due to the embedding of Q waves in noise. Therefore, the signal was first filtered before peak detection. To suppress noise, Savitzky–Golay filtering was applied. Peaks with amplitudes between −0.2 mV and −0.5 mV were identified as Q waves. Heart rate was computed using equations (1) and (2).

$$\text{Mean RR range} = \frac{1}{N-1} \left(\sum_{i=1}^{N-1} [R \text{ peak}_{i+1} - R \text{ peak}_i] \right) \times \frac{1}{f_s} \quad (1)$$

$$\text{BPM} = \frac{60sn}{\text{Mean RR range(sec)}} \quad (2)$$

For the example signal shown, the sampling frequency (fsf_sfs) was 500 Hz, and the analysis window length was 2000 samples. Within this window, four R peaks were detected, yielding $N=4N=4N=4$. For mean RR interval estimation, the positions of the R peaks were first identified. Using equation (1), the mean RR interval was calculated as 1 s. Applying equation (2) resulted in a heart rate of 60 beats per minute.

Based on these calculations, the following measurements were performed, single-channel ECG data acquisition, PPG signal acquisition, NIBP measurement and pulse detection

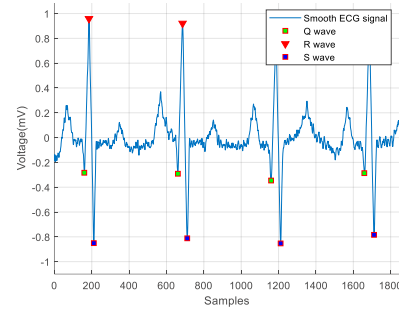


Figure 6. R Peak Detection

The compressor inflates the cuffs upon receiving a trigger from the detected R peaks. The cuffs are divided into three main sections: lower leg, upper leg, and waist. Synchronization is achieved such that, following each R peak, inflation occurs within approximately 50 ms, followed by deflation over a duration of approximately 50 ms. The corresponding synchronization graph is presented in Fig. 7.

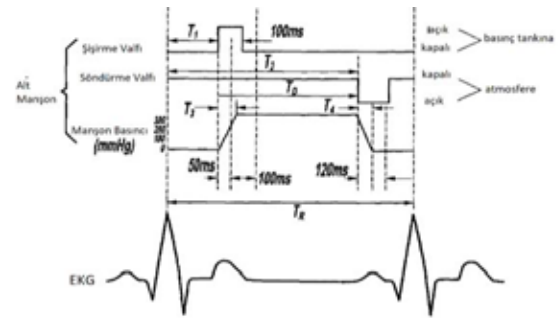


Figure 7. Synchronization Type

A graphical user interface (GUI) was developed on the Python platform to enable system control. The interface includes fields for patient information such as age, weight, and clinical complaints, as well as real-time vital monitor readings.

Prototype testing was conducted in two phases: preliminary validation on inanimate mannequins and subsequent evaluation on a volunteer subject. Figure 8 illustrates the system connection during volunteer testing.

Following the conceptual design stage, synchronized cuff inflation was implemented in three distinct zones—lower leg, upper leg, and waist—and calibrated to match inflation patterns documented in the literature [12]. Leak-proof, pressure-resistant drainage valves were integrated into the pneumatic circuit and mechanically coupled to the main assembly to ensure operational reliability under clinical conditions.

For initial mechanical validation, the cuffs were inflated to approximately 2 bar and applied to mannequin models. This stage focused on verifying leak integrity, pressure stability, and valve response timing. No leaks or pressure losses were

observed during multiple inflation–deflation cycles. Subsequent testing on a healthy volunteer confirmed proper cuff placement, secure fastening, and effective three-zone synchronized inflation. Inflation was triggered by R-peak detection from the ECG signal, with an approximate 50 ms delay from R-wave identification to inflation onset, followed by a 50 ms deflation period. These operational parameters were consistent with the intended control logic and demonstrated functional readiness for controlled clinical testing.

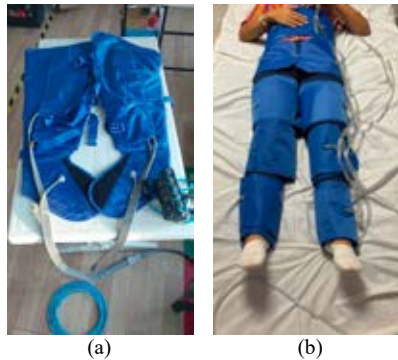


Figure 8. a) All Cuff System and Connection Cables b) Cuff Connection on a Volunteer

The design has been completed at Technology Readiness Level (TRL) 8. In future work, a Bill of Materials (BOM) will be generated from the critical design documentation, and IEC 60601 and IEC 60000 series electrical safety and electromagnetic compatibility tests will be conducted by an independent testing organization. Following these tests, an ethics committee application will be submitted to initiate clinical research studies.

IV. CONCLUSION

In this study, the electronic and software design processes of an EECP system were presented. The novelty of the work lies in transmitting the triggering command required for the EECP procedure to the hardware immediately after the R-peaks of the ECG signal. For this purpose, R-peaks were detected, and synchronized triggering was performed according to the venous return period (Figure 7).

The main limitation of the study is the absence of clinical trials. Since such trials will need to be conducted on patients with severe cardiac conditions, future work is planned in collaboration with clinicians and under the approval of an ethics committee.

In subsequent stages, medical compressors and vacuum systems with different power capacities, together with alternative air hose designs, can be integrated into the system. This will enable optimized operation for users of different body sizes and weights.

Additionally, a compact housing was designed to integrate the mechanical system, and the compressor–vacuum unit was

synchronized with the pulse information derived from the ECG signal. By combining essential vital sign monitoring functions—single-channel ECG, pulse detection, and oxygen saturation measurement—through OEM electronic modules and established engineering techniques, this study introduces a novel and cost-effective approach to EECP system development. The proposed synchronization innovation provides a new scientific perspective for future cardiological EECP device production.

ACKNOWLEDGMENT

The authors gratefully acknowledge the financial support provided by Marla Teknoloji Müh. San. ve Tic. Ltd. Şti. and its esteemed management for the execution of this study.

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