

A Dynamic Compression System for Improving Ulcer Healing: Design of a Sensing Garment

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Abstract—Venous leg ulcers remain a major problem in the United States, with spending reaching upwards of \$1 billion annually. Current treatment options center around the use of compression therapy, which is often delivered in the form of compression bandages, medical-grade stockings, or pneumatic devices. These technologies suffer from a lack of adaptability and/or portability, which may cause inefficient healing. A potential solution to this problem involves the use of an intelligent system that can vary the amount of compression delivered based upon measured physiological variables. A sensing system capable of monitoring both blood flow velocity and the extent of edema/swelling in the lower leg was built, and preliminary tests were conducted. The results of this testing show that the system can accurately detect small changes in leg volume, but is not sensitive enough to measure blood flow velocity. New techniques for measuring blood flow velocity are currently being sought. Upon successful implementation of these technologies, a larger scale study will be conducted in order to generate a robust data set from which a control system can be derived.

Index Terms—compression therapy, venous leg ulcers, auscultation, bio-impedance.

I. INTRODUCTION

Between 500,000-600,000 persons living in the United States are suspected to be suffering from venous leg ulcers [1]. Venous leg ulcers result from failure of the valves connecting the superficial and deep veins, which ultimately manifests as superficial venous hypertension [2], [3]. The skin capillaries cannot withstand this prolonged high pressure, leading to reduced oxygen delivery and the development of leg ulcers [3].

Treatment costs for this condition are substantial, with spending reaching upwards of \$775 million to \$1 billion annually [1]. A retrospective study conducted by Olin et al. set out to determine the source of out-patient expenses related to venous leg ulcer treatment. A strong relationship between total cost and the “duration of active therapy, ulcer size, and the presence of at least one comorbidity” was revealed [1]. Of these factors, the duration of active therapy can be most easily controlled; ulcer size and the presence of at least one comorbidity are related to the initial condition of the patient. Thus, in order to reduce patient costs, an inexpensive means of reducing treatment time must be developed.

Current treatment options for venous leg ulcers center around the use of compression therapy. Compression therapy is often delivered in the form of compression bandages, medical-grade stockings, or pneumatic compression devices. These technologies suffer from a lack of adaptability and/or portability, which may cause inefficient healing. A potential solution to this problem involves the use of an intelligent

system that can vary the amount of compression delivered based upon measured physiological variables [4]. With respect to venous leg ulcers, blood flow velocity and the extent of edema/swelling in the lower leg should be monitored in order to assess system performance. Arterial blood flow velocity is an indicator of oxygen and nutrient delivery to the site of the ulcer, and venous blood flow velocity is an indicator of waste removal from it. Additionally, if venous velocity drops too low, there is an increased likelihood for clot formation. The extent of edema/swelling is also closely tied to healing time because the ulcer will not close until swelling is reduced.

The sensing system described in this paper utilizes auscultation techniques to monitor blood flow velocity, and bio-impedance analysis to track the state of edema. Ultimately, this sensing system will be incorporated into a pneumatically-controlled compression stocking designed by the Carolan Company (Rural Hall, NC).

II. BLOOD FLOW VELOCITY MONITORING SYSTEM

The Blood Flow Velocity Monitoring System uses auscultation techniques to monitor changes in blood flow velocity. Auscultation has previously been identified as an acceptable technique for determining the quality of arterial blood flow, with highly sensitive microphones being used for monitoring as early as the 1970s [5]. In 1980, Wintermantel showed that differences in blood flow across a suture line could be resolved using two microphones (i.e. a diplo-microphone) [5]. Building on Wintermantel’s work, the Blood Flow Velocity Monitoring System utilizes an array of microphones to sense the arterial and venous pressure waveforms. These microphones are located at known intervals along the course of the vessel, allowing blood velocity to be determined by calculating the time delay between waveform peaks. The arterial pressure waveform occurs periodically at the same rate as the wearer’s heart beat (1-1.5 Hz), with the peak of the arterial pressure waveform corresponding to ventricular systole. The venous pressure waveform is also periodic at approximately the same rate as the wearer’s breathing (0.2-0.3 Hz), with its peak occurring during expiration [6].

A. System Design

An overview of the Blood Flow Velocity Monitoring System is shown in Figure 1. In order to sense the arterial/venous pressure waveform, an electret condenser microphone was used (WM-52BM, Panasonic). An initial amplification of 11x was applied to the incoming signal to raise it above the noise

floor of the circuit. At this point, the signal was split so as to preserve the raw signal in the case of future hardware changes. The signal was then low-pass filtered (2^{nd} order Butterworth filter, cutoff: 30Hz) to remove any high frequency noise. As the depth and size of the blood vessel are expected to affect signal strength, an adjustable, final stage amplification was applied to account individual differences. In order to avoid damaging the microprocessor (MSP430F149, Texas Instruments), negative signal components were eliminated through half-wave rectification; negative signal components reflect rebounding of the microphone bladder after a step impulse, and are not related to the pressure waveform. Both the rectified raw signal and rectified processed signal were fed to the microprocessor, which communicates serially with a PC. Further processing and analysis were carried out using MATLAB.

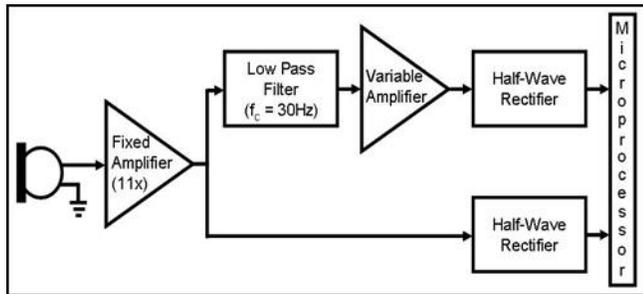


Fig. 1. Acoustic Blood Flow Monitoring System

A linear phase, 513-tap Parks-McClellan bandpass filter was used for arterial waveform filtering. This filter successfully removes movement artifacts resulting from breathing (i.e. the average adult respiratory rate is approximately 0.2-0.3 Hz) and any remaining high frequency noise while preserving important signal information (i.e. the average adult heart rate is approximately 1-1.5 Hz). Similarly, a linear phase, 513-tap Parks-McClellan low-pass filter was used for venous waveform filtering. This filter successfully removes any high frequency noise and attenuates the arterial pressure wave signal (i.e. the femoral artery and vein cross in some instances [7], [8]), while preserving important signal information.

B. Methods

The subject's blood pressure and heart rate were measured using an automatic blood pressure monitor (OMRON IntelliSense Digital Wrist Blood Pressure Monitor, Model: HEM-609ECK). The cuff was then removed and the subject was asked to rest their right arm on a table with their palm facing up. A manual blood pressure cuff was placed around the subject's upper arm (the cuff was not inflated).

The experiment was divided into two tests— measurement of arterial blood flow and measurement of venous blood flow. Subjects were given a 5 min rest between each test in order to ensure that blood flow had returned to normal. The experiment was immediately suspended if the subject experienced discomfort at any point during the test. At the conclusion of each test, the microphone was removed from the subject's arm and an ambient noise recording was made. In order to facilitate the measurement process (i.e. accessibility, subject comfort,

etc.), pressure waveforms were collected from the radial artery and the median cubital vein versus the femoral artery and vein. As the selected vessels are located more superficial than their femoral counterparts, the sensed pressure waveform is expected to be stronger; the experimental conditions were therefore representative of the ideal case.

For arterial testing, the radial artery was palpated, and a mark was made to denote its location. The microphone was then attached to the subject's arm (i.e. against bare skin) using a Velcro strap so that the center of the microphone was aligned with the mark denoting the location of the radial artery. The fit of the strap was adjusted to minimize the application of external pressure. The resting arterial pressure pulse was recorded (i.e. no cuff inflation) for approximately 20 sec using the Blood Flow Velocity Monitoring System (100 Hz sampling rate; total amplification: 49x). MATLAB was used for data processing, storage, and display purposes. The blood pressure cuff was then inflated to 160 mmHg in order to occlude arterial blood flow, and another measurement was taken. The cuff was deflated in 20 mmHg increments until it was again completely deflated (i.e. 0 mmHg), and measurements made. Each measurement was saved in a separate file.

For venous testing, the microphone was placed over the median cubital vein (at the elbow). The location of the vein was visually confirmed. The resting venous pressure waveform was recorded in the same manner as previously described (i.e. with the exception that a total amplification of 121x was applied). The blood pressure cuff was then inflated to 100 mmHg in order to occlude venous blood flow, and another measurement taken. The cuff was deflated in 20 mmHg increments until it was again completely deflated (i.e. 0 mmHg), and measurements made. Again, each measurement was saved in a separate file.

In order to determine if the Blood Flow Velocity Monitoring System could accurately detect arterial and venous blood flow, the RMS voltage of the signal was calculated at each pressure level. These values were normalized against the RMS voltage of the ambient noise. The normalized RMS voltages for each subject were plotted against the applied pressure level (note: data was further normalized against the largest measured RMS voltage for each subject for graphical display purposes). The time of signal appearance and disappearance was noted for each subject. For arterial testing, these values were compared to the subject's systolic blood pressure. For venous testing, these values were compared to pressures known to completely occlude venous blood flow (i.e. >50 mmHg). Fourier analysis of the raw data was carried out to assess where the strength of the signal lay.

C. Results

The Blood Flow Velocity Monitoring System serves as an accurate indicator of arterial blood flow. In all but one case (i.e. Subject 5), the appearance of a strong pulse signal occurred at the first instance when the applied pressure dropped below systolic pressure (i.e. arterial blood flow is permitted when the applied pressure falls below the systolic pressure level). For Subject 5, the pulse signal appeared one pressure step

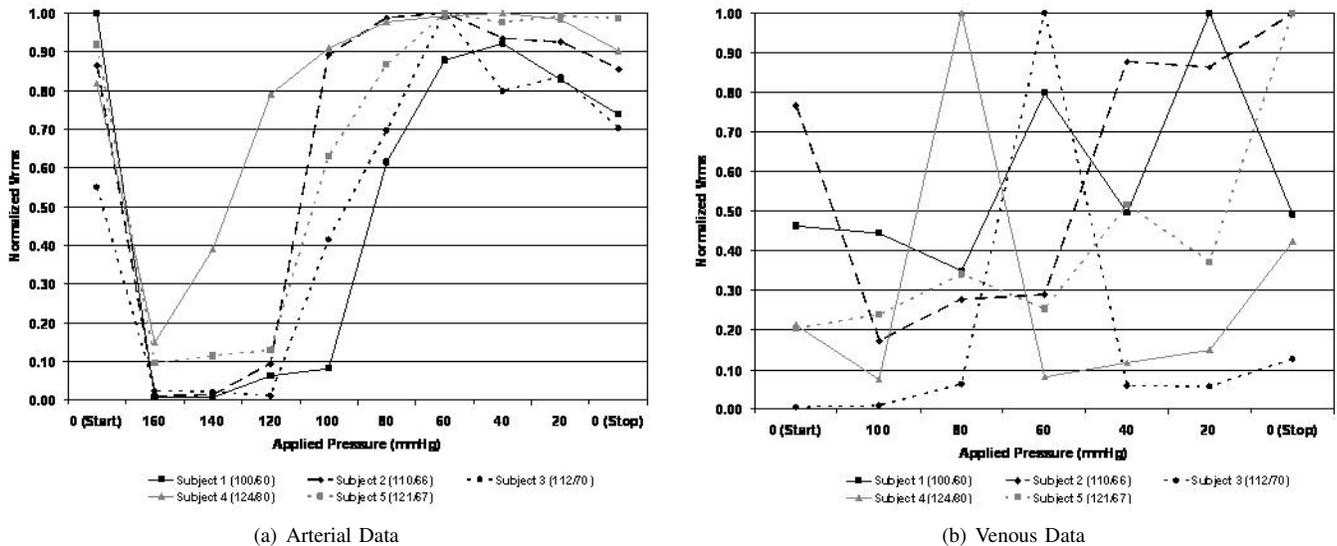


Fig. 2. Normalized Vrms vs. Applied Pressure

later than the recorded systolic pressure. This is not seen as problematic because the recorded pressure of 121 mmHg falls near the borderline of the experimental pressure intervals. Additionally, there is a ± 3 mmHg error associated with the automatic blood pressure cuff, so the subject's true blood pressure may be below 120 mmHg, as determined experimentally.

When signal power (i.e. measured as RMS voltage) is plotted against applied pressure, one can see a clear trend in the data (see Figure 2). When zero flow conditions are achieved, signal power drops dramatically. This is to be expected, as only noise is being measured. When systolic pressure is reached, there is a marked increase in signal power due to the appearance of a pulse, although this level is generally below full flow conditions. Signal strength continues to increase until diastolic pressure is reached, and then appears to level off or drop slightly. Again, this is to be expected because full flow should be regained when the applied pressure falls below the diastolic pressure.

The Blood Flow Velocity Monitoring System is not able to detect venous blood flow. The pressure waveforms recorded during full flow and zero flow conditions appear markedly similar (i.e. both appear to be noise). Additionally, the expected periodic changes due to breathing were not observed in the full flow signal. Fourier analysis of the full flow data shows that the strongest frequency component is well above the expected 0.2-0.3 Hz. This confirms that venous blood flow is not being measured.

Signal power also increases/decreases in a seemingly random fashion (see Figure 2). This further supports the claim that venous flow is not being measured, as there should be a clear difference in signal strength between full, partial, and zero flow conditions. In fact, the signal actually grows stronger as pressure is increased from 0 mmHg to known zero flow conditions (i.e. >50 mmHg) in the majority of subjects tested. A large difference in starting and stopping RMS voltages (raw data) was also noted for Subjects 3, 4, and 5. This is not to

be expected, as both measurements were taken with 0 mmHg of applied pressure. Such a large discrepancy was not noted when measuring changes in arterial flow. Additionally, the venous signal power and ambient noise signal power were of comparable magnitudes, indicating that the signal lay near the noise floor of the circuit.

III. EDEMA MONITORING SYSTEM

The Edema Monitoring System uses bio-impedance analysis to monitor changes in lower limb volume. Briefly, impedance analysis techniques take advantage of the fact that the resistance of an object is known to vary inversely with cross-sectional area. Assuming that the length of the object remains constant, differences in volume (i.e. resistance) can be measured by applying a known current and monitoring the respective change in voltage (i.e. $V = IR$). With respect to bio-impedance, two pairs of electrodes are attached to the body. A high-frequency (i.e. 10-100 kHz) low amplitude AC current is passed between the outer pair of electrodes, and changes to this signal are measured by the inner pair of electrodes (see Figure 3). A stimulating frequency of 50 kHz is traditionally used, although different properties can be measured by varying this frequency [9].

A. System Design

An overview of the Edema Monitoring System is shown in Figure 3. In order to generate a 50 kHz AC signal, a microprocessor (MSP430F149, Texas Instruments) was used to produce a 50 kHz square wave. This square wave was then low-pass filtered (4th order Butterworth filter, cutoff: 50 kHz) to produce a sine wave, which served as an input to a precision current source. The current source was implemented using the enhanced Howland topology. In the enhanced Howland circuit, the current output is a function of the voltage input, and the output impedance is a function of the selected resistor

values [10]–[12]. The resistor values selected for this application limited current to less than 1 mA RMS under normal operating conditions (i.e. industry standard), and ensured that the supplied current did not exceed the safety limitations imposed by IEC 2007 60601-1. The final circuit also included a $0.1 \mu\text{F}$ DC-blocking capacitor for patient safety (i.e. a DC voltage being applied to the skin may result in irritation or burning) [13].

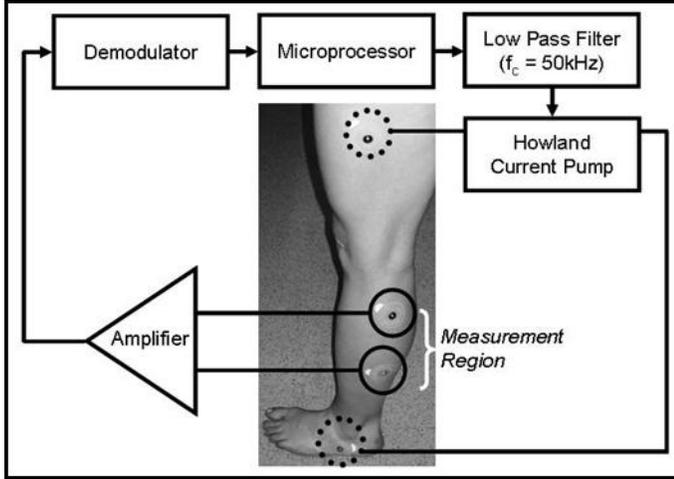


Fig. 3. Overview of Edema Monitoring System

The generated current was applied to the limb through the transmitting electrodes. The distorted signal was detected by the sensing electrodes, and amplified using an instrumentation amplifier (INA332, Texas Instruments). The output of the instrumentation amplifier reflects the voltage across the measurement area. If the supplied current is known and assumed to remain constant, the impedance of the segment can be calculated using Ohm’s Law. Therefore, changes in impedance are indicated by an increase/decrease in the measured signal amplitude (i.e. DC level). In order to recover the DC portion of the signal, demodulation techniques were used. A simple demodulator was formed by placing a low-pass filter (i.e. with a low cutoff frequency) in series with a full-wave rectifying circuit. The demodulated signal was then sampled at a rate of 100 Hz by the microprocessor (MSP430F149, Texas Instruments; 12-bit A/D), which communicated serially with a PC. Further processing and analysis were carried out using MATLAB.

B. Methods

The impedance of the lower leg was measured using the Edema Monitoring System. Four electrodes (CLEARTRACE ECG Electrodes, ConMed) were applied to the lateral side of the subject’s leg using a standard configuration for medical testing (see Figure 3). A constant current of $95 \mu\text{A}$ RMS was applied through the outer pair of electrodes (i.e. located on the mid-thigh and foot) [14]. The voltage potential was recorded between the inner pair of electrodes (i.e. spanning the calf). Care was taken to maintain similar electrode placement over the course of the testing period.

A manual blood pressure cuff was then placed around the subject’s lower thigh, and the leg elevated to hip-height.

The impedance of the lower leg was measured for 1 min (i.e. resting measurement). The cuff was then inflated to 100 mmHg in order to permit arterial, but not venous blood flow (i.e. artificially induced swelling). The impedance of the lower leg was measured in this state for 1 min (i.e. swelling measurement). The pressure was then released, and the impedance of the lower leg measured for 1 min (i.e. recovery measurement). Please note that the impedance of the lower leg was also measured during inflation and deflation of the cuff, but these measurements were not used for analysis purposes. This process was repeated 4 more times (i.e. total of 5 trials), with a minimum of 30 min between each trial to ensure full recovery.

The average resting, swollen, and recovered voltage potentials were computed for each trial. The voltage potential is related to leg volume by Ohm’s Law. These values were compared using a series of t-tests. A plot of impedance versus time was also created by splicing together each measurement segment (i.e. resting, cuff inflation, swelling, cuff deflation, and recovery). The data was then passed through a low-pass filter (second-order Butterworth filter, cutoff = 0.1 Hz) to facilitate observation of overall trends.

IV. RESULTS

The Edema Monitoring System was able to reliably track small changes in leg volume resulting from artificially-induced swelling. An example of the Edema Monitoring System output recorded during this experiment is shown in Figure 4. The average 5 sec interval data (i.e. adopting the measurement protocol that will be used in the actual system) is shown in Figure 4. Clear differences in the measured voltage potentials for each condition are evident in these plots.

The average voltage levels recorded between the two inner electrodes during resting, swollen, and recovered conditions are shown in Table I. In all cases, the recorded voltage was largest during the recovered condition. This difference was found to be significant with respect to both the resting ($p = 0.005$) and swollen ($p < 0.001$) conditions. Furthermore, with the exception of Trial 3, the recorded voltage was larger during resting versus swelling conditions. The data for Trial 3 is suspect, as the average voltage levels are lower for all three conditions as compared to the other trials. This may indicate poor contact between the electrodes and the skin. Despite this anomaly, a significant difference between resting and swollen conditions was still found ($p = 0.03$).

TABLE I
AVERAGE VOLTAGE LEVELS FOR EACH CONDITION

Trial	Resting (V)	Swelling (V)	Recovery (V)
1	1.55	1.53	1.57
2	1.56	1.55	1.58
3	1.48	1.49	1.53
4	1.53	1.51	1.56
5	1.52	1.50	1.54

V. DISCUSSION

Two sets of experiments were conducted in order to assess the performance of the purposed sensing system during

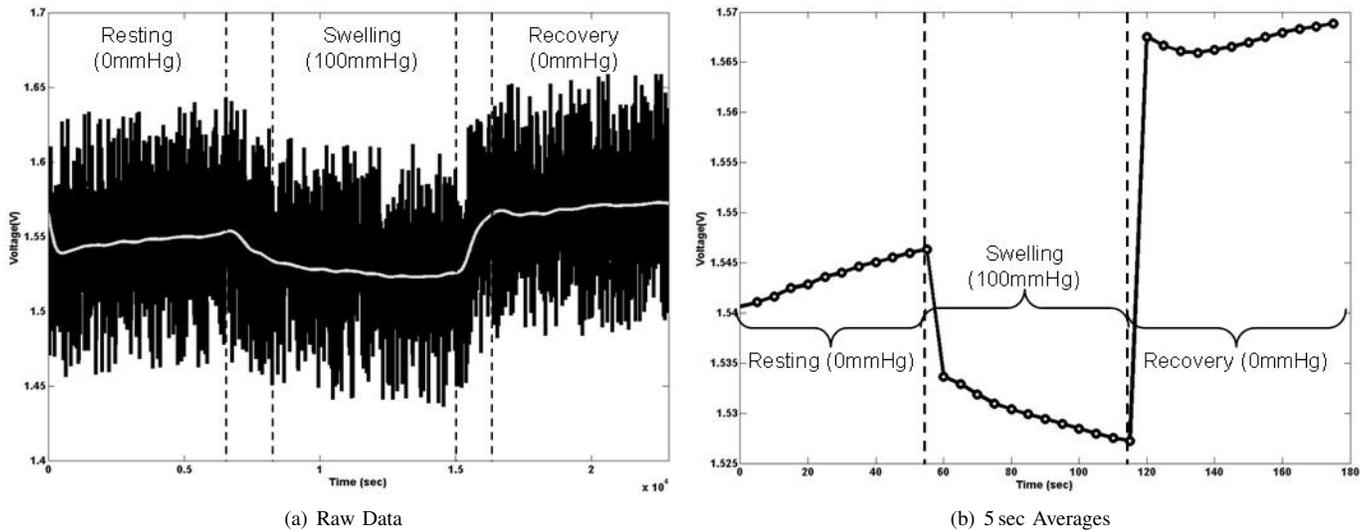


Fig. 4. System Response to Artificially-Induced Swelling

realistic use scenarios. The Blood Flow Velocity Monitoring System was found to acceptably resolve arterial, but not venous, blood flow. With respect to arterial blood flow, there was a clear difference in signal power between known full and zero flow conditions, with increases/decreases in signal strength following predictable patterns. This trend was not, however, observed for venous blood flow. Instead, signal strength increased/decreased in a seemingly random fashion, with no clear difference between full and zero flow conditions. Additionally, the signal power did not reside in the frequency band of interest (i.e. 0.2-0.3 Hz).

The Edema Monitoring System was capable of measuring small changes in leg volume. When venous return from the lower leg was blocked, there was a statistically significant difference in the recorded voltage potential. The recorded potential was lowest during swelling, indicating a decrease in resistance to current flow resulting from an increase in volume. Additionally, volume changes were apparent upon examination of the voltage trace. The only cause for concern is related to the integrity of the contact between the skin and the electrode. As was observed in Trial 3 of the second experiment, poor contact might result in lower quality results (i.e. small changes may not be accurately resolved). In actual use, contact may be improved because the compression stocking would serve to hold the electrode against the skin.

Based upon the results obtained in these experiments, a more accurate means of sensing blood flow velocity is needed. This could be accomplished through the use of a portable, CW Doppler Ultrasound system, similar to the one developed by Molina et al. [15], [16]. Upon successful demonstration of a proof-of-concept system, both the Blood Flow Velocity Monitoring System and the Edema Monitoring System will be integrated into a single sensing garment. This integrated system will then be tested on patients with a variety of vascular conditions in order to generate a robust data set. The amount of applied pressure will be varied, and the corresponding changes in blood flow velocity and the extent

of edema/swelling measured. These variables will serve as inputs to a neural network that will be used to make control decisions concerning the amount of pressure to deliver. In parallel to this effort, additional sensors (i.e. temperature and perfusion) will be integrated in order to provide the controller with additional information. Upon successful implementation of this technology with knee-length stockings, the market will be expanded to include all medical-grade compression stockings, thus benefiting the maximum number of people.

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