MESOTHERAPY DEVICE FOR ESTHETIC APPLICATIONS

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Abstract: This article describes a complete system prototype to be used in aesthetic mesotherapy. The system is composed by two main blocks: a Master block, whose chief component is a CPU, which provides the user interface and a Slave block, implemented with a micro controller and a wave generator, which produces the appropriated voltages and currents compatible with the mesotherapy treatments. The whole system is powered by a 12V power supply and the output signal has a voltage that range between -54 V and 54 V. The output signal is composed by the overlap of two frequencies: the first one is selected in the range from 1.2 kHz to 1.8 kHz and the second one is in the range from 0.07 Hz to 2 Hz. The system is being tested in clinical environment with real patients showing very good promising results.

1 INTRODUCTION

Mesotherapy is a non-surgical cosmetic medicine treatment that employs multiple injections of pharmaceutical and homeopathic medications, plant extracts, vitamins, and other ingredients into the subcutaneous fat. Mesotherapy injections are purported to target adipose fat cells, apparently by inducing rupture and cell death among adipocytes. (Tosti, 2007).

Mesotherapy has presented new opportunities in aesthetic medicine because it is a non-evasive treatment capable of reducing cellulite and weight (Ward, 2002). Into these two capabilities are also included protocols like Cellulite, Obesity, Facial and Body Contouring. Besides these applications, the mesotherapy can be applied in other treatments such as acne, arthritis, sports injuries, ulcers, vein treatments and rheumatology.

In this article we report some aspects of the design and fabrication of a device prototype that allows mesotherapic treatments. These treatments, based on different layers of skin, are able to reach 9cm of depth (e.g. hypoderm or fat most affected area).

The basic working principle of the device consists on a set of electrical pulses that are applied on the skin surface, through two treatment electrodes: a roll-on, used as active electrode, and a glove, used as return electrode, originating two reactions:

- Expansion of the cell pores and epidermis alignment, as shown in figure 1;
- The electric field attracts the cream molecules into the skin. The cream can be positively or negatively charged, as shown in figure 2.

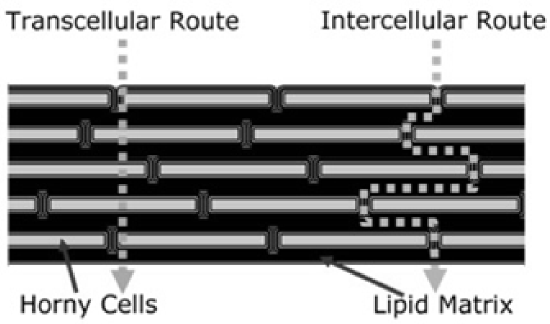

Figure 1: Transcellular and intercellular routes of treatment cream through the lipid matrix.

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The main objective of this project is the development of a device prototype capable to perform the treatments referred above. In order to do that, it is necessary to:

- Develop a programmable signal generator;
- Due to practical issues the system supply voltage cannot exceed 12V, while the output signal may contain peaks that reach 54V;
- Develop the appropriate safeguards to avoid patients injuries;
- Develop a user-friendly interface to be used by technical personal without expertise on electronics and informatics;
- Develop a flexible system able to introduce new types of treatments without hardware upgrades;
- Develop a system capable to report any type of anomaly;
- Develop a system able to work 24h/7day.

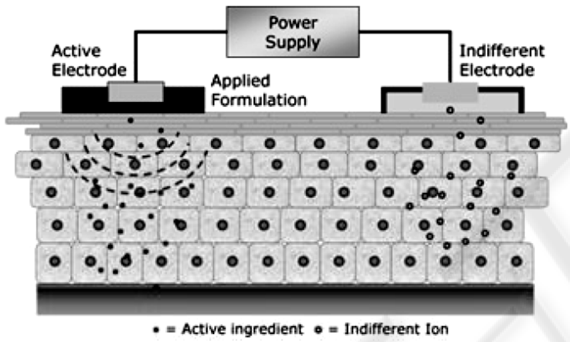

Figure 2: Electric field generated by the electrodes It is visible the response of cream particles along the hypoderm.

2 BACKGROUND

This project is being funded by several companies and its main goal is to develop an hardware prototype capable of performing mesotherapy, reducing the technical expertise needed in treatments handling. On the other hand, it is possible to expand the functionalities of this prototype in order to achieve other treatments in the area of electrotherapy, without the need of adding new hardware components.

With the support provided by ISAVE University (ISAVE, 2008) we have been able to incorporate all the information required to produce the proper signals required to generate other therapy types of currents:

- Galvanic Currents;
- Russian Electrical Simulation (Ward and Shkuratova, 2002);
- Transcutaneous Electrical Simulation;
- Iontophoresis Current (Carter, 2003);
- Pain-Free Currents (Johnson, 2003);
- Electroforoporation Currents;

Thus, despite the development of this prototype was targeted for aesthetic medicine, it can also achieve other types of treatments since the platform accepts other signals by changing only a few setup parameters.

Electronic devices applied on esthetical medicine must have a huge factor of accuracy and quality, mostly the ones that are in direct contact with the patient, leaving no space for errors.

In the past, all the options taken in the development of these devices are mainly related with the chosen materials and the methods that were used to maximize perfection, quality, reliability and performance.

In order to achieve the best results during a treatment, the equipments must guaranty a clear and precise signal output with a perfect repetition and very low error tolerance.

In the esthetical medicine area there are different types of treatments which can be held as a resource of mesotherapy:

- Anticellulite;
- Located anticellulite;
- Antistretch;
- Antiflaccidity.

Each type of treatment needs a special signal with a polarity, which may be positive or negative, depending on the cream used. In all treatments the applied signals obeyed to eq. 1:

$$SIGNAL = ((HF * LF) + LF) \qquad (1)$$

where HF is the high frequency component, whose value ranges between 1.2kHz and 1.8kHz, and LF is the low frequency component, whose frequency ranges from 0.07Hz to 2Hz (its period ranges between 0.5 and 14 seconds).

Galvanic current is the base of this treatment. It always circulates in the same direction (the voltage is always positive or is always negative), once each cream has its own polarity. Therefore the system must guarantee this characteristic for the generated voltage, that is, the system must follow the algorithm:

Positive Polarity:

```
If ((HF * LF) + LF) < 0
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```
   then SIGNAL=0
Else
   SIGNAL = (HF * LF) + LF
```

Negative Polarity:

```
If ((HF * LF) + LF) > 0
   then SIGNAL=0
Else
   SIGNAL = (HF * LF) + LF
```

3 SYSTEM ARCHITECTURE

The general system architecture proposed in this paper is a master-slave structure since there are two control units: a high-level control unit (master) and a low-level control unit (slave).

The high-level control unit or central processing unit (CPU) is responsible for supporting the user interface: exchanging and processing the necessary information between the user and the low-level control unit. The low-level control unit, whose main component is a micro controller, is responsible to convert digital data, received from the high-level, to analogical signals that are applied directly to the patient skin, through the connection devices.

Figure 3 shows the system architecture.

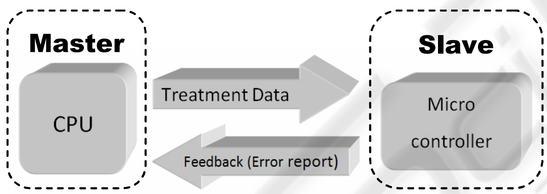

Figure 3: System architecture. The CPU operates as master and the micro controller operates as slave. The micro controller functionalities are controlled by the CPU.

Despite the system is of master-slave type, a feedback from the output to the micro controller is used in order to allow the detection of some malfunctions.

The Master block is composed by a processor unit, a touch-screen and an Ethernet interface, while the Slave block is constituted by a micro controller, a step-up converter, a driver, an H-bridge, a filter and the patient's protection circuit. Both blocks communicate by means of an USB interface.

The following paragraphs describe, in detail, the most important functions shown in figure 4.

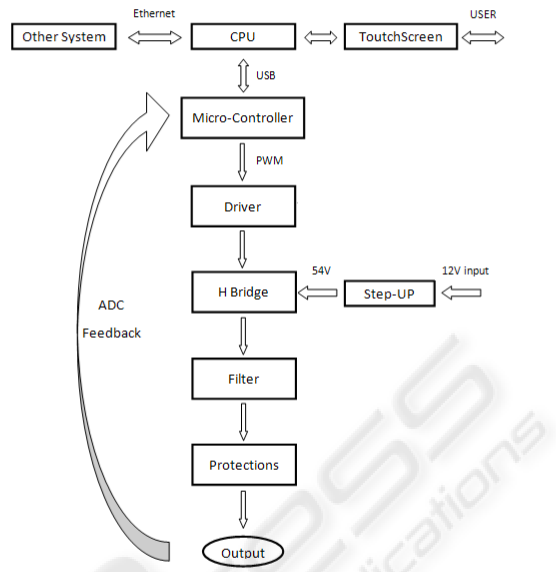

Figure 4: Block Diagram of the device internal structure and the links between the various sub-systems.

The CPU is the head of the system, responsible for gather all the data, coming from the user-interface console, process it and calculate the appropriated coefficient vector that will be used by the micro controller to produce the corresponding output signal with a PWM (Pulse Width Modulation).

If we consider that the technical personal do not have expertise in informatics and electronics technologies, it is important to provide an intuitive graphical interface. For this purpose, it was used a touch-screen monitor to operate the device in an intuitive way. The programming language used was C++, associated to an Open GL platform in order to satisfy several requirements, namely the real time operation, the support for micro controller systems and the attainment of the maximum graphic potentialities of the system.

It is important to refer that this platform is based on a Linux operating system, due its great potentialities for real time operation associated with the advantage that it is a free software, making easier and cheaper the system commercialization.

Another particular feature is the system dynamism, which enables firmware upgrades and interconnection with other devices in order to allow a huge range of treatments.

All interconnections between CPU and other functional blocks are bidirectional, allowing a continuous feedback that enable instantaneous detection of any anomaly.

The micro controller is responsible for assembling the information, sent by the CPU, in order to drive the H-Bridge. It calculates the PWM ON / OFF times, generating the desired signal to the system output.

The micro controller uses an 8MHz crystal. In order to generate a PWM signal that does not reach frequencies higher than 30kHz, the sampling frequency used by the micro controller is about 17 times higher than the frequency of the output signal to ensure a low ripple at the filter output.

An AT90USB1287 low-power CMOS 8-bit micro controller was used (Johnson and Tabasam, 2003), based on the AVR with 64/128K bytes of ISP Flash and an USB device controller with full speed and low speed data transfer support, enhanced RISC architecture. By executing powerful instructions in a single clock cycle, the AT90USB1287 achieves throughputs approaching 1MIPS per MHz allowing the system designer to optimize power consumption versus processing speed.

The interface between master and slave blocks is achieved by means of a USB connection due to is large bandwidth and Plug and Play interoperability. A full-duplex low speed (1.5Mbit/s) data rate connection is used that guarantees up to 512kbit/s of bandwidth in each direction.

The Bus topology used is the Reduced Host Topology showed in figure 5 (Atmel, 2007).

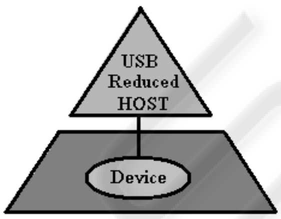

Figure 5: Reduced Host Topology. A reduced host controller has a unique USB port and does not handle full USB tree with hub. It means that a reduced host controller is designed to handle a unique point-to-point connection with an unique USB device.

Its main characteristics are:

USB Host:

- There is only one host in any USB system, and it operates as the “master” of the USB bus;
- The USB interface to the host system is referred to as the Host Controller.

USB Device:

- An USB device operates as a slave node on the USB bus;
- Thanks to the USB hub (that also operates as an USB device) up to 127 devices can be connected on the USB bus. Each device is uniquely identified by a device address.

It would be only necessary to implement a more elaborated connection topology if the micro controller interacts with more than one device because it would be necessary to guarantee that it communicates with the correct device. As this system is composed by just one device, the use of the simplified topology facilitates the implementation of the connection between the CPU and the micro controller.

The micro controller output signal produces a peak voltage of 3.3V. To manage an effective treatment it is necessary to amplify this signal to higher levels, such as 54V. To carry out this task it was implemented an H-bridge with two quadrants, allowing the change of the signal output polarity according to the corresponding treatment. The H-Bridge was implemented by means of L6225 DMOS Dual Full Bridge chip which combines isolated DMOS Power Transistors with CMOS and bipolar circuits on the same chip (STMicroelectronics, 2007). Figure 6 shows the schematic diagram of this circuit.

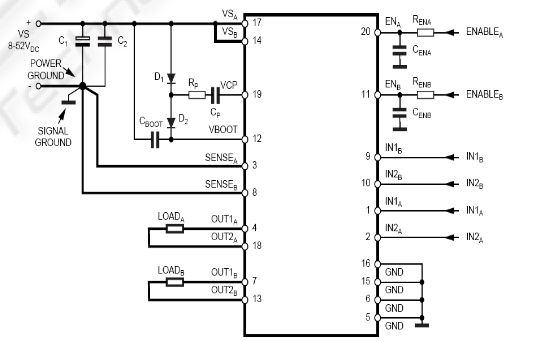

Figure 6: H-Bridge circuit based on BCD technology. Combines isolated DMOS Power Transistors with CMOS and bipolar circuits on the same chip.

The signal output is a sum of two components: a low frequency of 0.07Hz (Period = 14s) and a high frequency of 1.8kHz. A low-pass active filter, with a Q factor of 2, and a cut-off frequency of 2kHz were used. Thus the filter output no longer presents the high frequency components, produced by the PWM modulator, and all variations of the sign are smoothed. Figure 7 shows the output waveform of the PWM modulator. Figure 8 depicts a time expansion between B1 and B2 bars of figure 7.

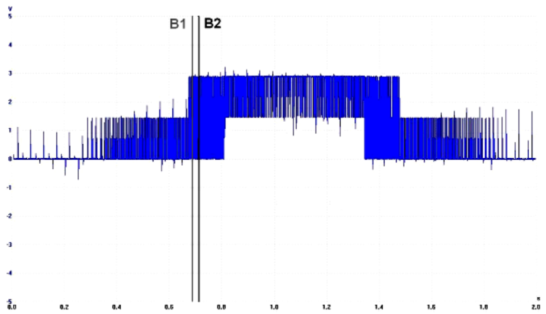

Figure 7: Signal obtained at the output of the H-Bridge circuit, with 2s in time axis and 5V in voltage axis.

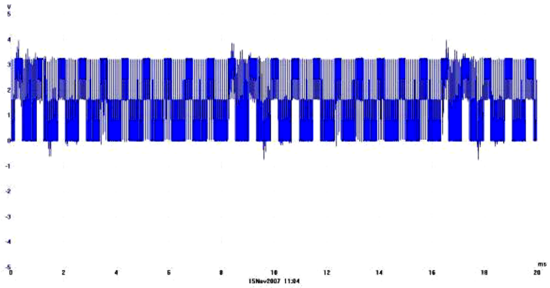

Figure 8: Signal of figure 7, expanded with 20ms between B1 and B2 bars.

Figure 9 shows the low pass filter response. Figure 10 depicts a time expansion between C1 and C2 bars of figure 9.

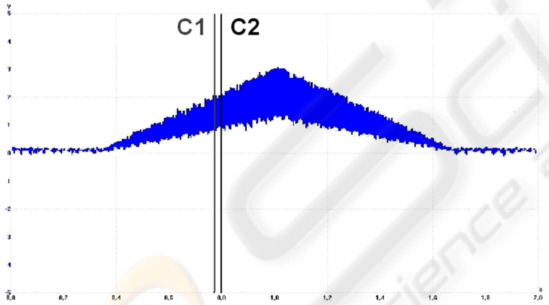

Figure 9: Signal obtained at the system output. It corresponds to the signal of Fig. 8 be low-pass filtered, with 2s in time axis and 5V in voltage axis.

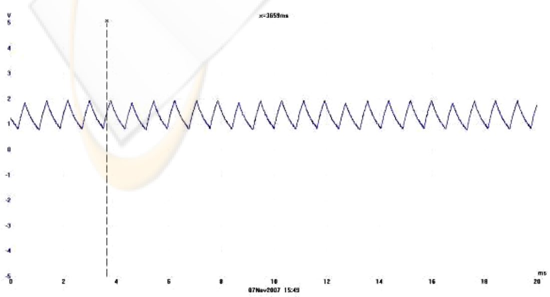

Figure 10: Signal Signal of figure 9, expanded with 20ms between B1 and B2 bars.

Standard requirements (RSIUEE, 1974), imposed on medical equipment, does not allow that the power system, responsible for generating treatment signals, have input voltages higher than 12V. Nevertheless, to obtain the expected results, the signal output must produce peaks of 54V. This task is achieved by means of a step-up circuit which provides up to 54V linear voltage with small ripple and 500mA of maximum current. In the present application the current can not exceed 50mA. The step-up circuit is implemented with the LT1680 (Linear Technology, 2007) whose schematic diagram is shown in figure 11.

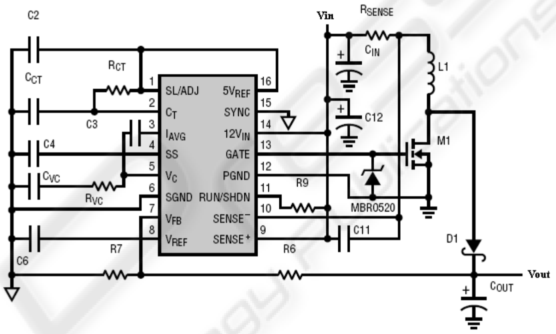

Figure 11: Step-Up circuit. High power, current mode switching power supply controller optimized for boost topologies. The IC drives an N-channel MOSFET switch for DC/DC converter up to 60V output.

All equipment must obey to security rules imposed by responsible entities. Therefore, in addition to the main objective, that is, the mesotherapic equipment development, we have also to ensure the safety of the patient. In this way, it was introduced a current limiter before the signal output. When the current reaches higher values than 30mA, the circuit output voltage is lowered, as it is shown in figure 12.

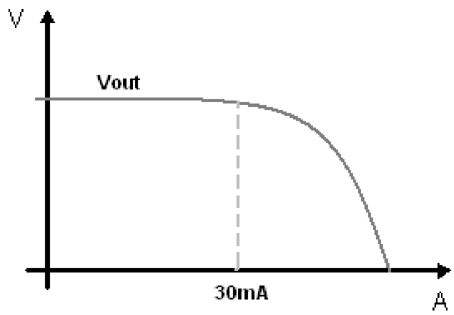

Figure 12: Output voltage versus current. For currents above 30mA the system protection responds by reducing the output voltage.

4 PROTOTYPE

To conduct the necessary system tests, a prototype was built where the methodology described in this article was implemented. This prototype is now being used in the aesthetics mesotherapy treatments in order to get a functionality and efficiency diagnosis of the device. Therefore, it is necessary that this prototype show the full potentialities of the system but also show simple and functional user-interface to simplify the use by the technical personal. Figures 13 and 14 show some pictures of the prototype.

Figure 13: Device internal circuits.

Figure 14: Device external appearance.

5 CONCLUSIONS

This article described a complete system prototype for use in aesthetic mesotherapy. The system is composed by a master-slave architecture in which the master block is based on a CPU and the slave block is based on a micro controller. The first system prototype is already tested and fabricated in laboratory conditions with performances that correspond to the expected ones. It was also tested in a clinical environment, with real patients. The results of these tests are more or less subjective once consist on the opinion of the technicians and patients, but almost all consider the performance of the prototype as good or very good. As a future work, the prototype software will be adapted to perform lymphatic draining or muscle stimulation treatments.

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