μMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem

FUSE Application Experiment 29853
Dissemination / Demonstrator document

Microcontroller-based Multifunction
Electro-stimulation SYStem

Modular approach and microcontroller technology reduce costs and increase reliability in the Electric aesthetic applications

AE number: 29853
New Technology: Microprocessor
Industrial sector: Medical & Surgical Equipment and Orthopaedic Appliances (3310)
Contact TTN: COREP
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AE abstract

VIP s.r.l., a 14 employees company, operates in the field of aesthetic devices since 1970. Its main field of interest is the design and distribution of electric-aesthetic appliances, as muscular stimulators, directed to professional users. Our company manufactures and distributes electric aesthetic devices addressed to professional users. It has a good knowledge of the kind of equipment requested by the market, joined to a great experience on the effect of electric stimulation on human body. We have some experience with the design of analog circuits, but up to now the design process of new appliances has been performed in strict collaboration with external consultants. Our products are still sold all over the world, but once more due to marketing strategies.

The company exports world wide to resellers with particular concern to Great Britain, Hong Kong, India, Portugal , Russia. Besides the company exploits and favors a franchising scheme.

Our portfolio includes different kinds of electric neuromuscular stimulators, photo therapy equipment, and dedicated machines for some special aesthetic treatment like peeling and hair removal.

As stated above, all our equipment were based on analogue electronic circuits.

The AE allowed the design of an advanced electronic neuro-muscular stimulator to integrate three different products of the First User into a single equipment and to package, them in several different combinations without any functionality loss, and with better satisfaction of customers requirements. The first use of microcontroller and SMT technologies provides the new product with the following advantages:

- Introduction of an LCD visualisation and a smart card reader, which provides our customers with new features and a better looking for our stimulator, an issue quite important in our particular market
- Reduced technical assistance costs, both from the point of view of personnel training as for spare parts warehouse reduction. Moreover, self test features of the new device allow self test and self diagnosis of the equipment itself.
- Production cost fall due to the merging of the market share of three different appliances.
- Customers training time reduction, by mean of an intuitive graphical interface.
- Increased flexibility, through software customization and strong defense against intrusion and reverse engineering
- Reduced time to market for new similar appliances, obtained using a modular approach for the design of the target of the AE.

The AE duration was 9 month, for a total funding of 57.25 kEUR.

Expected break-even time is about 6 months, return on FUSE investment can be estimated more than 15 times in 5 years and more than 5 times considering the global investment.
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**Keywords and signature**

**Keywords:** Microcontroller, electric aesthetic device, SMT, LCD, electronic stimulation, software configuration

**Signature:** 2-14045551460 1 3310 1 33 I

1. **Company name and address**

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Company logo:

2. **Company size**

The company has 14 employees and an annual turnover of 1,38 MEURO. Three technicians are devoted to electronic appliances development and technical assistance. They have a discrete knowledge of analog and digital electronic circuits, but no experience at all with microprocessor technology. The technical staff does not include any electronic engineer.

3. **Company business description**

Our company manufactures and sells electric aesthetic devices addressed to professional usage. We strongly exploit the franchising scheme world wide

The manufacturing of our products is generally subcontracted. Products are directly sold to resellers. Installation and maintenance are provided by our technical assistance.

Our company produces mainly 7 electric aesthetic appliances:

- Transion
- Isogeii
- Linfogei
- Cromogei
- Exfoliance
- Depigei
- Visocomplex
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Our products can be grouped into four lines according to the specific usage:

1. Muscular electric stimulators including the TRANSION, ISOGEI
2. Specific Beauty problems treatment including: LINFOGEI (venous and lymph drainage), CROMOGEI (based on electromagnetic waves)
3. Peeling and skin cleansing include VISOCOMPLEX, DEPIGEI (based on short waves)
4. Skin Abrasion treatment includes EXFOLIANCE (uses micro-crystal flow)

The company is present on the field of electric aesthetic devices since 1970 and has a good knowledge of the kind of equipment requested by the market, joined to a great experience on the effect of electric stimulation on the human body, obtained with direct experimentation as with feedback from the franchising network.

From the point of view of electronics, we have some experience with the design of analog circuits, but up to now the design process of the electronic part has been performed with external consultants.

Our estimate for the market size at world level is of the order of 100 M€ and the trend is growing.

As it will explained better in the next paragraph, the driving forces for this special kind of equipment is the aesthetic look and this is the feature where the technology innovation should play the major role.

4. Company markets and competitive position at the start of the AE

Company turnover in 1998 was around 1.38 MECU.

The following diagram table shows the share of 1998 invoiced amount:

<table>
<thead>
<tr>
<th>1998 TURNOVER SHARE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRANSION 36%</td>
</tr>
<tr>
<td>ISOGEI 19%</td>
</tr>
<tr>
<td>LINFOGEI 25%</td>
</tr>
<tr>
<td>CROMOGEI 6%</td>
</tr>
<tr>
<td>EXFOLIANCE 8%</td>
</tr>
<tr>
<td>VISOCOMPLEX 2%</td>
</tr>
<tr>
<td>DEPIGEI 4%</td>
</tr>
</tbody>
</table>

Fig 1

The new product replaces three different appliances:

1. Transion
2. Isogei
3. Linfogei
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Transion is an equipment fat to reduce which encountered a great success both on the Italian market and on the international one. The name Transion in the field of aesthetics was so well known that the first similar appliances from competitors are often presented as ‘Transion-like’. On the trail of its success the other two devices, Isogei and Linfoge were designed i, with a similar technology.

Nowadays, the bulky and unreliable analogue technology, the size and the external asset, as well as the lack of the requested flexibility and easy modification, make these appliances obsolete. Nevertheless, they are still sold all over the world, but once more due to marketing strategies, like special offers and very active collateral training and post sales services.

The trend of VIP turnover and gross margin in the last three years is reported in the following graphs:

Fig. 2

A reasonable estimate of the current market share is:

- **Domestic market 0.9%**
- **International market 1%**

The major reason for the scarce presence in the domestic market is to be found in the cash-flow constraints; the too long payment terms offered and usually accepted in the Italian market are not bearable for VIP. The firm policy had therefore been addressed to concentrate its business activity mainly with more trustful customers in the foreign markets which finally lead its presence abroad to become extremely relevant.

Although the market of electric aesthetic appliances is very fragmented and market figures data are not publicly available, we are well aware of our competition represented by the following companies:

- Sorisa - Spain
- Nemectron - Germany
Our major competitors use since a few years more advanced technologies that allow them two main advantages:

- A much more appealing view (thanks to nice LCD displays) of the equipment, an issue which is of paramount importance with our customers, where the aesthetic of the user interface is the strength of the product
- The flexibility offered by the programmability of the advanced electronics to easily change the functions to be implemented, which enable to develop a dedicated user interface with an OEM market approach

These choices of the competitions have placed VIP in a difficult position, making their equipment, although reliable and sold at a reasonable price, less appreciated by the customers (aesthetic institutes and beauty farms) because of the lack of the said mentioned features.

This also caused a decrease of the gross margin since the only way to keep the market share was to decrease the selling price (to distributors abroad and to final customers in Italy)

It should be noticed that the general expenses are very high for this product category, particularly the one associated with advertising and customer training. In fact due to the particular kind of market VIP is operating into, we must offer a very appealing image of the company and this translates into higher expenses for the premises (offices, furniture, appliances). An attractive advertising is also a strength in front of the competition and that meant that a lot of money should be spent for promotion and PR.

Finally VIP is very proud of its training offered to its customers. VIP is known in its field as an international training and demonstration center and is worldwide appreciated in this role.

VIP organises periodic training stages for its customers which are guest of our company for a fortnight in order to understand the usage of our equipment and the kind of aesthetic treatments they allow.

The total general expenses vary with the considered model but they are roughly between two and three times the simple production costs which makes the margin for sales to distributors to oscillate between 10% and 19%.

It is nearly impossible to compare competitors’ costs and prices to ours because the characteristics of the appliances are quite different, but we can affirm that the used technologies and technical features are generally less advanced than ours.

Our main customers are the resellers located in the following countries:

- Great Britain
- Hong Kong
- India
- Portugal
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- Russia

As can be seen our market is mainly extra Europe where we reached a good reputation. In fact a strong point of our present line of products is that they are present in the market since several years which can prove their reliability and the clients’ trust. However, a weak point is that they are very similar to those produced by low technology competitors based on the same technology and moreover they are not able to offer LCD visualisation. Consequently it becomes difficult to tie the clients to the mark. Another weak point is that the higher technology competition products offer a better design and a more appealing look.

5. Product to be improved and its industrial sectors

The current products which are substituted by the new product are three neuromuscular stimulators named Transion, Linfogei and Isogeii.

They generate electric pulses suitable to stimulate non-voluntary muscular contraction, to obtain aesthetic improvement of the human body, through fat reduction, fat shaping, and lymphatic drainage. The pulse are applied to the human body through electrodes.

Even if similar functions are performed by the different appliances, their have internal architecture is quite different, mainly due to customization reasons. In fact, the first models have been introduced on the market around 1970, but they followed a completely independent evolution, due to market requests. In the following pictures the logo ej which is a VIP trademark. The Transion has 12 outputs, which deliver a variable amplitude square wave to the electrodes. The frequency of the square wave is selectable between 400 and 600 Hz, and is periodically switched off at a rate of 0.3 - 2 seconds. The square wave has an average value equal to zero. This kind of signal is particularly well suited to passive gymnastic and physiotherapy. A block diagram of this appliance is visible in Figure 1.

![Block diagram of the Transion](image)

Fig. 4: Block diagram of the Transion
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**Fig. 5: photo of the Transion**

The square wave generator (OSC), controlled by a timer programmable from 1 to 99 minutes (TIMER), feeds the six output sections (CH1-CH6), which include safety circuits to limit the maximum current in the output and a potentiometer to vary the output amplitude. The Zero Voltage Detector (ZVD) is a circuit which disables the ‘start’ command of the timer if the output potentiometer are not at their minimum. This is to guarantee that the output voltage was at a minimum when the treatment is started, as required by safety regulations.

The Isogei equipment has only two outputs, which deliver a train of negative pulses with 220 us width at a repetition rate variable between 20 and 55 Hz. This kind of stimulus is well suited to obtain isometric contractions of the muscle. The user can vary the amplitude of the pulses, according to the sensitivity of the subject of the treatment as to the muscle on which the treatment is applied. The internal block diagram of this appliance is depicted in Figure 2.

![Figure A2: Block diagram of Isogei](image)

**Fig. 6: photo Isogei**

A pulse generator (PULSE), controlled by a timer (TIMER) set by the user through some switches (KEYS), delivers train of pulses to a high voltage amplifier, which in turn feeds the output circuitry (CH1 and CH2). These one include an analog memory to store the programmed output level amplitude for the duration of the treatment. The output voltage and currents are monitored by a circuit (ALARM), which reset the timer if peak and rms values exceed safety limits. At last, two voltmeters (VM) display the current peak level, for operator reference.

The Linfogei has 12 output channels, which deliver a train of negative pulses with 120 us width at a repetition rate of 50 Hz. These pulses can be synchronized to the systole or diastole phase of the cardiac cycle, rendering it suitable to obtain a lymphatic drainage effect.

A block diagram of Linfogei is depicted in Figure 3.
A pulse generator (PULSE), controlled by the user interface block (USER INT) and synchronized to the cardiac cycle of the subject through the sensor input, delivers train of pulses to a high voltage amplifier, which in turn feeds the 12 output channels. These ones include a potentiometer to independently vary the output level. The output voltages and currents are monitored by a circuit (ALARM), which reset the system if peak and rms values exceed safety limits. At last, two voltmeter display output signal levels.

The user interface exploits an externally developed microprocessor based board which handles some push buttons and 7-segment LED displays.

This block does not perform any function related to the generation of the output signal, except enabling the pulse generator at the start of the treatment and disabling it at the end. More important, no knowledge is available inside the company related to the real operation of this section, as it has been bought as a turn-key solution.

All three equipment use analogue discrete components mounted in PCB through-hole technology. None of them embeds microprocessors or similar programmable devices.

*The reasons to innovate*

The main reasons that motivated the development of a new product introducing a much more advanced technology are all market driven: this means that in general what should be improved are not the performance, (which in reality are improved because for example there is the possibility to drive a major number of channels), but instead the flexibility and the programmability and, most of all, the capability to drive a smart LCD display which can impress our potential customers.

- A modular approach is required to allow future development with new type of signals with different voltage and current level, too.
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- New equipment must satisfy EC regulation for emission and EMC
- The feature used to monitor the outputs according to safety regulations must be extended to allow self-test and self-diagnosis of the appliance, to disable it in case of fault.
- The new device must interface to additional modules to allow development of new marketing strategies.
- The system must exhibit a graphical user interface, represented by mean of a reasonably large Liquid Crystal Display (320X240) to allow a more user friendly and appealing user interface
- It must supply the output waveforms by mean of digital synthesis techniques, to enable the easy generation of a wide range of frequency and pulse width of the output signals under total software control.
- The new equipment must be able to interface to additional modules, such as PC interfaces and SmartCard readers.

Besides the above mentioned reasons our main goal is to increase the customer satisfaction by introducing a new generation of much more appealing and flexible machines less prone to failures and reliability problems at very reasonable prices.

Of course we expected also to reduce our manufacturing and testing costs

The main technical specifications of the new equipment are the following:

<table>
<thead>
<tr>
<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power supply:</td>
</tr>
<tr>
<td>Operating temperature range:</td>
</tr>
<tr>
<td>Umidity:</td>
</tr>
</tbody>
</table>

The main functional and electrical characteristics of the TRANSION output card are also given in comparison with the one of the current instrument.
Table 1 Comparison between the current and new product features

<table>
<thead>
<tr>
<th>Feature</th>
<th>New</th>
<th>Current</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output number</td>
<td>8 (all isolated with independent software programmable amplitude)</td>
<td>6 (not isolated, amplitude programmable with trimmers)</td>
</tr>
<tr>
<td>Output type</td>
<td>Square waves (programmable duty cycle)</td>
<td>Fixed duty cycle (50%)</td>
</tr>
<tr>
<td>Output frequency</td>
<td>400 - 600 in programmable 0.75 Hz steps</td>
<td>Fixed frequency 400 or 600 Hz</td>
</tr>
<tr>
<td>Pause between trains</td>
<td>Programmable</td>
<td>fixed 2,7 or 4 sec</td>
</tr>
<tr>
<td>Action duration</td>
<td>Programmable</td>
<td>Fixed 1.9 sec</td>
</tr>
<tr>
<td>Maximum output current</td>
<td>45 ma Max software programmable</td>
<td>45 ma Max Adjustable with trimmers</td>
</tr>
<tr>
<td>Maximum output voltage</td>
<td>60V Max software programmable</td>
<td>60V Max Adjustable with trimmers</td>
</tr>
<tr>
<td>Load resistance</td>
<td>200 - 700 Ohm software check of the human body load</td>
<td>200 - 700 Ohm</td>
</tr>
<tr>
<td>Safety</td>
<td>BF type Class 1</td>
<td>BF type Class 1</td>
</tr>
</tbody>
</table>

It should also be noticed that the new equipment allows also an automated operation of the ISOGEI instrument were the same pulses are multiplexed on different stimulation points without no external intervention.

Another important issue addressed from the innovation is the EMC certification for the LINFOGEI which was not possible to obtain for the previous product.

6. Description of the technical product improvements

The system target of this AE is able to reproduce the functionality’s of the three existent appliances described above into a single equipment, reconfigurable according to the customers needs.

The idea to transmit to our customers is the feeling that this new equipment represents a true break point with past technology, and this should also be reflected in the external appearance.

Therefore, the system has a suitable graphical user interface, represented by mean of a reasonably large Liquid Crystal Display, which, on customer request, can exhibit color features. Input from the user is received through keys related to icons represented on the display close to the pushbuttons. As the company has a wide international market, the used output language is customizable at no extra cost, as a function of the target distribution country.

Another task is the generation of output waveforms by mean of digital synthesis techniques, to allow arbitrary shapes generation and a wide range of frequency and pulse width of the output signals under total software control. Output signal amplitude is controlled by software, too. The use of digital signal
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synthesis completely eliminates the need for channel by channel calibration during the appliance test phase, reducing manufacturing costs.

A modular approach has been requested to allow accommodation of future development which requires new type of signals, with different voltage and current levels, too. Additional output devices, such as motors, RF generators, etc. are easily controllable by the base equipment, allowing further functionality expansion in the future.

The new equipment satisfies the severe EC regulations applicable to this kind of devices, including lock out of the outputs in case of limits exceeding due to either component faults, or operator misuse.

Another new feature of the designed electronics is in the field of maintenance: the capability to monitor outputs according to safety regulations, must be extended to allow self-test and self-diagnosis of the appliance, in order to disable it in case of fault, and to guide technicians to identify damaged components.

At last, the new equipment is now open to embed additional modules, such as PC interfaces and SmartCard readers, to allow the development of new marketing strategies, such as the monitoring of the devices from a centralized computer or the rental of treatments instead of equipment’s.

A block diagram of the designed equipment is depicted in Figure 4.

Fig. 9: Block diagram of the new equipment

A more complete block diagram showing one of the possible combination is shown in the following picture.
Here CM represents the Control Module PM is the Peripheral Module and CM2PM Is the Control – Peripheral interface also able to manage the RS232 and the card reader. A flash memory allocated in the Control Module board allows for an easy programming through the RS232 interface of the main equipment parameters and the menus structure on the LCD display.

The chosen architecture with three distinct microcontroller units, while increasing only 1.1% the total cost of the unit, allows the best modularity and expandibility since it decouples almost completely the monitor and control functions from the stimulating signal implementation part.

Through the RS232 serial communication available in the control to peripheral module, the machine configuration can be easily loaded from an external PC.
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Fig. 11 Block Diagram of the Control Module (CM)

Fig. 12 Block Diagram of the Peripheral Module (PM)
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The control module (CM) manages the user interface through the LCD screen and the push buttons. Moreover it controls the three peripheral modules (Pmn) on a common system bus. It is built around an 8 bit microcontroller, with extended external memory to store the great amount of data needed for the graphic user interface. Up to six peripheral modules can be contemporary presents on the system bus. Each peripheral module drives 4 output channels with arbitrary waveform, and samples up to three analog inputs. The block (PSU) is the power supply unit, which fed every other block in the appliance. Safety requirements are satisfied by the peripheral module itself. In fact each one is built around an 8 bit microcontroller, which drives the output DAC and reads back the output signal information, to track the status of the equipment.

A photograph of one of the output boards is given in the following picture where the transformers used to monitor the output currents are also visible.

![Control board photograph](image)

**Fig. 13: Control board photograph**

A photograph of the whole equipment set-up (the final choice of the external body appearance has still to be performed and will be available for the definite release of the demonstrator document) is also given.

**Fig. 14 New Equipment Set-Up** The advantages of the newly implemented electronic circuitry can be
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so summarised:

- **Much improved reliability due to the extended usage of SMD components and the reduced number of solder joints**
- **Improved EMC performance due to the smaller size if the PCBs and power and signal loop (fulfilment of the LV recommendations requirements)**
- **Complete separation between the signal and the power sections which are also galvanically decoupled**
- **Automated synthesis generation of the output waveforms with full programmability of their frequency, duty-cycle, width and amplitude (much increased operating frequency)**
- **Introduction of self diagnosis capability with consequent reduction of the testing and maintenance costs and increased safety features**
- **Very user friendly interface with graphical menu driven LCD**
- **The system is now open to further customer requests with the introduction of new PC interfaces, (RS232, RS485), smart card readers which can be easily modified under the software control.**
- **The brain of the equipment is made with a microcontroller which is a technology that can be protected from unauthorized electronic intrusion and project copying**
- **The architecture was designed following a modular approach and it offers enough flexibility to allow a (re)configuration of the multifunctional machine so that it can be packaged in several combinations.**

7. **Choices and rationale for the selected technologies, tools and methodologies**

The company decided to design an appliance with surface mount and microcontroller technology based on the following considerations:

First of all this is the technology that allows to realize the desired features (modularity, flexibility, programmability)

Other possible technologies are ASIC and FPGA and we made a thorough analysis with the assistance of our subcontractor and the TTN, in order to evaluate the most suitable technology.

For the selection we based on the following considerations:

- **Medium volume productions do not allow the use of ASIC’s or Gate Array solutions, even if they could lead to an even reduced risk of copying for the project**
- **FPGA technology is not suitable due to the complexity of the task algorithms and the need to have A/D and D/A conversion. Moreover, there is no need to have high speed of the digital part, due to the very low frequencies used and thus the added cost of this solution is not justified**
- **MCM and microsystems technology is not needed, as there is no need for low power or small size of the equipment. And no specific request for special sensors.**
- **Instead the usage of a microcontroller is the key to obtain a great improvement in functionality’s with reduced or null increase of the cost of the equipment as it appears clear from the following issues:**
The introduction of a microcontroller, for signal synthesis allows to obtain an increase in reliability of the product, due to the elimination of long term drifts in critical parts of the equipment.

From the point of view of security against product duplication, most modern microcontrollers includes efficient techniques against code downloading from the internal memory.

Due to system requirements, a microcontroller with medium-high internal complexity is needed, to make easier the management of user interface graphics. On the other hand, looser requirements are derived from the signal generation and analysis sections of the design. An 8 bit device, running at 8 MHz seemed to be the best choice. Anyway, the modular approach allows the change of the microcontroller used, if further computational power or addressing space would be needed.

The 68HC1X family from Motorola seemed to offer the requested trade-off between price and performance. Specifically the major capability (memory and interface features) of HC11 was used in the control part, while a lower performance model was used in the power management section.

Surface Mount Technology was a forced choice since, for current microcontroller technology, the IC packaging cost is a dominant factor: small plastic surface mount packages are a shortcut to lower production prices. However we also considered the further advantaged of reduced PCB size and improved reliability.

The complexity of the project has been overcome thanks to the choice to use a modular approach for software design, too. First of all, the inter module communication protocol has been established, reserving slots for message complexity expansion. After that, the firmware’s of PM (Power Monitor) and CM (Control Monitor) have been independently developed. Concerning CM, the choice of an high level language (C in particular) was mandatory, due to the high complexity of graphic display management. PM firmware, on the opposite, was directly written in assembly language, to allow greater flexibility in the output signal handling, and better speed performance.

The tools used in the project development were:

- A complete PCB CAD system, able to perform integrated schematic capture, symbol definition, netlist extraction, geometry definition, layout design, and automated cross-check against schematics. The PCB design has been performed ‘in house’ to have care of EMC problems.
- An assembler has been used to generate the code for the peripheral modules. It is freely distributed by Motorola, for the family of microcontrollers used.
- A public domain C compiler has been used to compile the firmware of the control module. This choice seemed to be the best one, since a prototype of the control module itself was used as development support tool, and the choosen compiler allowed a complete customization in front of the used. hardware No commercial emulator was able to accomplish this task, due to the requirement of a great amount of external memory to store the user interface data.

8. Expertise and experience in microelectronics of the company and the staff allocated to the project

From the point of view of electronics, the company had some previous experience with the design of analog circuits, but up to the start of the AE the electronic design of new appliances had been demanded to external consultants. No expertise was available in the company regarding the development of solutions based on microprocessor technology.

The staff allocated to the project was composed by two technicians, involved in the production and maintenance, and by a manager, involved in marketing and administrative tasks.

9. Workplan and rationale

The chosen design methodology is derived from the need to develop and test the system in a very short time as compared to the complexity of the project. This requirement led to an as paralleled as possible
design, in which compatible design phases are overlapped whenever possible. For the same reason, no high level system simulation has been performed. The adopted methodology can be divided in three different phases:

1. **Design and Pre-test:** The system has been designed and tested in the First User laboratory, to verify the fulfillment of the electrical specification and the respect of the safety requirements. It is important to notice that the microcontroller holds the full software control of the signal generation and of the user interface, in such a way it was possible to design, realize and test the hardware in parallel with firmware development (hw/sw codesign).

2. **Aestheticians evaluation and test:** The system is being evaluated and tested by professional aestheticians in the Demonstration Center (CD) of the First User, in strict contact with the technicians. This phase allows the testing of the firmware in a real operative environment, and the tailoring of firmware to the preferences of non technician professional personnel.

3. **On field and conformance tests:** The developed system, now with a high degree of confidence on its reliability, is going to be distributed to some beta sites in different countries, to verify its compatibility with different environment conditions, and to enlarge the statistical database of performed test, defects, and remedies. Due to the complexity of the software, a software for statistical defect analysis is planned to be used, to track and forecast the product reliability. Meanwhile, tests have been performed by the First User with the advice of a certified body for the verification of EMC limits conformance\(^1\), and for safety certification. In fact, in order to be commercialized in EC countries, the product must fulfill the EN60601 specifications.

As the product is strategic for the FU company, great care has been used to define the project workplan, allowing for possible delays with acceptable economical drawbacks. From this point of view, the maximum acceptable delay was estimated 4 month. In this period the FU could continue to sell the original appliances, with a reduced turnover of 0.04 MECU. Possible foreseen causes of delay were considered the manufacturing delay, design inconveniences discovered during the test phases, and the problems with conformance tests to EC regulations. Specification writing time (2 months) is quite large, but this phase was very important in avoiding following delays, due to incomplete design definition. In any case, eventual development redundant time has been used to anticipate not predictable small delays in next phases of the workplan. This consideration was true especially for the testing phase, too, due to the complexity of the implemented equipment.

It follows the description of the planned workplan

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\(^1\) (notice that in the prototyping phase only the so called precompliance has been carried out, since all the remaining certification was left for the industrialization phase as it is explained in the dedicated paragraph)
WP1: Management

Objectives:
1. To develop an efficient project management through the whole AE
2. To assure a periodical provision of the reports needed for project monitoring
3. To help TTN to extract dissemination materials from the deliverables and to spread them to the community

Duration: 9 months.

Measure of success: Deliverables completed and available according to the foreseen schedule

Tasks:
1. Task 1.1: Project management (1 month) [Responsibility to First User]
2. Task 1.2: Project status reporting (9 month) [Responsibility to First User]
3. Task 1.3: Dissemination (9 month) [Responsibility to First User]
4. 

WP2: Training

Objectives:
1. To give the First User an effective training on different project management and technology choices issues
2. To provide the First User with a good technical insight of the different design steps.

Duration: 7 months.

Measure of success: Ability of First User personnel to understand key aspects of designing with microcontroller technology.

Tasks:
1. Task 2.1: Project management training (2 months) [Responsibility to subcontractor]
2. Task 2.2: Technical training specific courses (2 months) [Responsibility of subcontractor]
3. Task 2.3: On field technical training (5 months) [Responsibility of subcontractor]

WP3: System analysis and specifications

Objectives:
1. To define all functional specifications of µMESYS product
2. To provide the electrical specifications at interfaces
3. To design user interface behavior.
4. To define testing specifications.

Duration: 2 months.

Measure of success: Availability of a complete and stable specification document.

Tasks:
µMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem

1. Task 3.1: Functional specifications (0.5 months) [Responsibility to First User in strict cooperation with subcontractor]
2. Task 3.2: Interface electrical specifications (0.5 months) [Responsibility to First User in strict cooperation with subcontractor]
3. Task 3.3: User interface design (0.5 months) [Responsibility to First User in strict cooperation with subcontractor]
4. Task 3.4: Test specifications (0.5 months) [Responsibility to First User in strict cooperation with subcontractor]

Risk assessment:

Duration of this WP has been overestimated, to allow the inclusion of every possible specification change during this period. From the end of WP3, no further change is allowed, to eliminate possible delays due to unneeded redesign.

WP4: HW/SW design

Objectives:

1. To develop the complete design of hardware and software of the µMESYS system
2. To design electrical schematics of microcontroller system and to develop the prototype.

Duration: 8 months.

Measure of success: Working prototype system fully satisfying required specifications.

Tasks:
1. Task 4.1: Hardware/Software system partitioning (0.5 months) [Responsibility to subcontractor]
2. Task 4.2: Signal generation and analysis firmware development (2 month) [Responsibility to subcontractor, FU receives on the job training]
3. Task 4.3: User interface firmware development (2 months) [Responsibility to subcontractor, FU receives on the job training]
4. Task 4.4: Auto-test, auto-diagnosis and ‘safe-if-fail’ firmware development (2 months) [Responsibility to subcontractor, FU receives on the job training]
5. Task 4.5: Schematics development (2 months)
6. Task 4.6: PCBs design (1 month)
7. Task 4.7: PCBs fabrication and system assembly (1 month)

Risk assessment:

The most of time was assigned to PCB design and fabrication to allow manufacturing delays. Anyway, this time can parallelly be used to refine the firmware, especially from the point of view of user interface (debugging related to unexpected user inputs).

WP5: Prototype test and evaluation

Objectives:
µMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem

1. To test the µMESYS prototype, with particular concern to auto-test, auto-diagnosis, and ‘safe-if-fail’ features.
2. To verify compliance to EC regulations
3. To verify satisfaction of professional aestheticians with intensive use in the Demonstration Center (CD) of the First User.

**Duration:** 3 months.

**Measure of success:** Compliance to EN60601 standard; professional aestheticians satisfaction.

**Tasks:**

5. Task 5.1: Laboratory tests (1 month) [Responsibility to First User in strict cooperation with subcontractor]

6. Task 5.2: Security and EMC tests (1 month) [Responsibility to First User]

7. Task 5.3: CD tests (1 month) [Responsibility to First User in strict cooperation]

**Roles and responsibilities:**

*First User Man hours and Subcontractor’s costs*

As far as the effort is concerned, the company involvement in the experiment was larger than expected. About 25 days more than estimated were spent in the project especially in training and design.

This was mainly due that the person firstly involved in the AE resigned from VIP and another technician had to be trained on the new technology and design issues.

The effort of the subcontractor was more focused on the testing phase which was distributed along the whole development.

The effort of the First User and the cost for the subcontractor are summarised in the following table.
### First User Effort [men/hours] and Subcontractor Cost [kEUR]

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### Timing Diagram

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VIP s.r.l. 24
μMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem

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VIP s.r.l. 25
Workplan Changes

The workplan did not suffer any major change during the project since reasonable safeguard time was allocated in the original planning and we suggest this as a general strategy to other companies to avoid unwanted delays and shifts in the different phases.

The main change was in the testing phase which was slightly extended and also anticipated in the last phases of the design.

EMC testing had to be postponed to the first weeks of September because of the Summer holidays and the first tests with aestheticians were completed at the end of September.

As a final change the whole training task was performed by the subcontractor for design assistance although in the original proposal a training course was planned to be found in the Europractice TBPS catalogue.

The reasons for this change were:
- No Europractice suitable course was available in the period
- Training was mainly given during the project
- A unique subcontractor was used in the whole project (Hexis took also care of the manufacturing process)

It should be noticed in any way that the design and lab tests were concluded almost on schedule (about 10 days delay due to Summer vacations) and we consider it a very important success of our first project management experience.

10. Subcontractor information

Vip since several years was advised from its consultant of the need to change the technology of its equipment.

A very good cooperation existed since many years as it is proved by the fact that the consultant was sent to several exhibitions to investigate on the technology used by the competition.

VIP trusted this consultant also because during the past years it had the opportunity to demonstrate a high degree of confidentiality, an issue which is a must in the company market.

The TTN met the consulting company and approved the partnership at the beginning of the AE.

Summarising, the choice of subcontractor was based on the following considerations:
- The Subcontractor offered its services to the First User from about 4 years, with full satisfaction from both sides.
- Its knowledge in the field of electric aesthetic appliances, as from a general point of view, as regarding specific devices produced by the First User, guarantees an optimal information exchange during the whole duration of the AE.

Here we give an idea of the technical background of our subcontractor where it is easy for another company to guess the requested expertise for a similar application.
µMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem

Our subcontractor specialized in advanced services in the field of electronics and information technology. It offers to customers its expertise in the analysis and design of integrated hardware/software solutions, both standalone and network oriented.

Examples of industrial commitments are:

• Design and realization of electronic medical equipment’s, such as neuromuscular stimulators and electric miographic signals portable recorders. Interfacing of these equipment’s to computer systems.

• Design and realization of precision measurement systems for aeronautical industry, such as contact goniometers for wing incidence angle measurement.

• Design and realization of equipment’s for security systems.

• Assistance to the customer for the conformity of electronic equipment’s to the EC directives in the field of security and electromagnetic compatibility.

• Design and realization of an integrated information system for territory surveillance, based on collection and presentation of symbolic data, superimposed to the cartography of the national territory. The result is obtained by mean of a country-wide computers network.

• Design and realization of information systems for the collection and statistical analysis of clinical data coming from sites distributed on the regional or national territory.

• Installation and on field assistance of firm computer networks.

More important in all these activities the subcontractor used an on the job training approach with the assisted with a real grow of the technology management capability from the assisted company staff.

Contracts

The usual procedures was used. An offer was requested and negotiated with the subcontractor. An order was issued where the specification list was taken as an annex. Payments were associated to the availability of the corresponding deliverables.

At the end of the application experiment, IPR is fully owned by the company (Vip s.r.l.).

11. Barriers perceived by the company in the first use of the AE technology

VIP was very reluctant at the beginning in deciding to innovate the core of its aesthetic equipment by introducing a completely unknown technology.

Several questions had to obtain a proper answer:

1. The technology suggested by the TTN could be managed by our company

2. Was our previous subcontractor the most suitable for this development (we wanted to keep it but we were not sure)

3. How to set up a sound plan for the development

4. Did we have the requested technical staff to ensure the proper know-how follow-up of the AE

Before the µ MESYS project, VIP had the feeling that a great risk would be involved in developing a programmable solution for its aesthetic equipment.

The main reasons for that perception were

• The electronic technology know how in the company was very low
It was difficult for the management to plan a development with a technology unknown to them.

There was an important lack of information on:

- Where to find the necessary experience to support the company in designing the new embedded system
- Where to procure the newly requested components (microprocessors, LCD display, RS232/485 interface and how to manage them
- Where to develop the design and manufacturing of the mixed through-hole/SMT PCB

Another important point regarded the training that VIP was supposed to give to its distributors on the main features of the equipment based on the newly introduced microprocessor technology.

Eventually it was also important to consider the customer (final user) attitude toward the new product. Would he/she appreciate the added features that VIP was going to introduce in its products?

12. Steps taken to overcome the barriers and arrive at an improved product

What really helped us in removing the initial obstacle was the awareness that the market really wanted a new more user friendly equipment with greatly enhanced flexibility and usability.

As far to the barrier mentioned in the previous chapter:

- the internal electronic know-how gap was reduced thanks to the training courses given to our technical staff
- The TTN was of great help during the whole development providing us with the necessary guidance for setting up the most suitable work-plan and with a careful monitoring forced us to respect the milestones and deliver on schedule the requested documents.
- The lack of information was faced with the following approaches:
  - We found a very flexible and skilled subcontractor who helped us to design the new embedded system, while ensuring an effective knowledge transfer to our company
  - The subcontractor assisted us and trained our commercial staff in interfacing the electronic component suppliers for quotations and orders.

To overcome the problem to have suitable electronic components, a pre design phase was introduced, in which cooperation between designers, producer and distributors has been able to identify components which have a sufficient market in the local country, so leading to price reductions, even for small quantities. Further investigation has been carried out, to check for possible acquisition of electronic devices directly from foreign distributors. In particular, some US companies offered small quantities of high tech devices at reduced prices, and with very fast delivery. The use of E-commerce on Internet has been a key point in the contact with foreign distributors.

- The same subcontractor took care of the prototype board processing and assisted us for finding a suitable PCB supplier for the mass production
- In order to prepare the market for the product evolution VIP was developing, the advice and suggestions, particularly for the user interface part was asked to some important customers, who were supposed in such a way to be in a better attitude towards the new product. The user interface was made as simple and friendly as possible thus simplifying the customer training phase.

We trusted the advice of the TTN which coincided with the suggestion of our subcontractor to use a microcontroller as the brain of our new product.
µMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem

Our subcontractor was already known to the TTN, but it supported our decision by discussing and validating the technical options of the subcontractor during the whole development.

The other cultural barriers have been overcome mainly through the assistance of the subcontractor. Careful investigations allowed to dissipate doubts about the first point (new technology manufacturing feasibility). Training activities of internal employees found sufficient time allotment by mean of substantial work reorganization in the technical departments of the FU, devoted to increase efficiency (a quality system was in development at the time of proposal preparation).

- Training time towards external people was reduced through a careful definition of an intuitive user interface of the new appliance.
- Last, predictable risks and delays were included in the work plan, to guarantee the desired time to market. The market itself is kept under observation to check for sudden changes and take suitable countermeasures.

13. Knowledge and experience acquired

We consider the outcome of the Application Experiment to have met in best way our expectations and perceive our technology management capability to be much improved because of it.

The main achievements that can be mentioned are:

- The First User has obtained a good knowledge about the process to follow to define design specifications for a new product.
- New contacts with electronic components distributors have been acquired. Modular design approach has been learned, suitable to perform analysis of different solutions for functionally separated sections of the design.
- Technician learned design approach to microcontroller technology, exploiting hardware/software co-design flexibility. Moreover, basic knowledge of digital signal synthesis and analysis techniques have been gained, profitable for future products development.

From the point of view of internally acquired knowledge, all the goals was met. And we are completely satisfied of the received training

14. Lessons learned

The company has identified the following problems which emerged during the Application Experiment:

- Reduced number of suppliers, on the Italian market, able to manufacture the new product, due to the use of SMD technology. It could lead to increased costs related to a reduced market competition of manufacturers.
- Amount of time needed for internal employee training (technician and aestheticians). This time must be subtracted to daily routine activities with impact on efficiency toward customers.
- Training time to be devoted to external people, such as technician in other countries, resellers, and professional customers. Additional costs due to knowledge redistribution must be better considered.
μMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem

- Time required to go to market with a fully engineered equipment. The steps needed to obtain formal approval from international bodies could lead to delays with respect to the scheduled times.

During the specification writing phase of the project, the first user has identified a possible problem, due to the fact internal personnel do not have any previous experience about ‘design specifications’, in particular about user interface design specifications. So, the request from subcontractor for needed technical information’s did not produce the expected results.

During the final phase of specification writing, a market analysis has been performed to find availability of high technology electronics components care of Italian distributors. Unlikely, a poor landscape appeared, as it is impossible to have samples, and then production quantities of devices which are not usually offered by resellers. Moreover, prices for hundredths to thousands of pieces are prohibitive. The shown cost is near twice the price declared by manufacturers inside United States, due to import taxes and distributors price policy.

Further lessons learned were related to technical and managerial matters:

- It is necessary to consider more alternatives from the beginning both in the design methodology and in the fabrication process.

- It is very important to reserve sufficient men-hours for understanding implications about component costs and supply and their use: introducing new technologies an expert guide in this field is necessary.

- It must consider the difficulties in finding small quantities of some high-tech components in European market and thus buying in USA, thanks to e-commerce.

- The subcontractor have assisted the FU in the realization of prototype, area non planned within its workplan. This event occurred because the leader of the staff allocated to the project left the project and the company. Security reasons imposed to not propagate any information about a strategic project for the FU company. The goal was achieved thanks to our subcontractor flexibility, with organization problems to respect steps and times of project.

15. Resulting product or process, its industrialization and internal replication

We are currently performing a research to choose a new manufacturing subcontractor for the volume production with automatic production lines because actual subcontractor is a service company that releases prototypes only. An agreement with any subcontractor maintains Vip s.r.l. the only owner of project. Maintaining the skills acquired in the company is a goal fundamental for us and we will organize internal stages for keeping and making deeper acquired knowledge.

Besides other great goal for our company is to upgrade the hardware and the software owned by company, with a co-operation between our staff and our design assistance subcontractor.

The new equipment is able to interface to additional modules, such as PC interfaces and SmartCard readers, to allow the development of new market strategies, such as the monitoring of the devices from a centralized computer or the rental of treatments instead of equipment’s.
The industrialization of \( \mu \)MESIS will be preceded by some preliminary steps:

- software full testing
- reliability testing of full system, hardware and software
- aestheticians evaluation and test
- on field and conformance tests
- certification to declare safety regulations and EC regulations compatibility, applicable to this kind of devices (CE, IMQ, VDE)

The estimated costs for industrialization are the followings:

- exterior case mould around EUR 6,000
- safety and EMC certification (CE, IMQ, etc) around EUR 8,000

It should be noticed that the most part of the certification will be carried out during the industrialization process, once all the particulars for the final production (housing, shielding etc.) have been defined and particularly on those specific equipment for which a preliminary order has been received.

- promotional and advertising materials around EUR 8,000
- First Low Volume Production costs around EUR 12,000

We estimate these steps will be completed around January 2000, because they require many man-hours for software assessment, but we have many doubts for exact certification time. Industrialization will be carried out with a different subcontractor, as shown above.

We started the industrialisation work in February and worked hard to find the most suitable housing for our product, taking into account the cost and the need of a good looking fitting.

At the end we decided that an hollow ABS column in which assemble a rack with a backplan and the needed boards would have been the right solution.

We are happy to say that after only six months from the conclusion of the AE we are now on the market and are collecting orders with a very promising expectative.

Indeed we have already delivered 4 equipment in Hong Kong and are in to ship other 2 to Los Angeles after a very successful exhibition there.

16. Economic impact and improvement in competitive position

The introduction of the new product should allow to increase both the domestic and international market shares. With the sale of one single module device including all the performance presently offered by three, the investment for the purchaser would be considerably lowered. As a consequence this will lead to increase the number of purchasers. Applied to the domestic market the lower amount of investment will also enable to envisage new payment formula to shorten payment terms so that also in Italy the sales could be strengthened.

After the introduction of the new product, a more stable market is expected with lower variations of the share due to VIP distributors. In fact on one side VIP will be able to treat from a strength position the price of its added value equipment, and, on the other the distributor will find a compensation to the
lower mark-up in the increased sales to the final customers. Of course, the increase of First User turnover is a consequence of the raise of revenue for the distributors.

No competitor suggest the integration of the three appliances in a single product. The introduction of such an object thus allows:

- reduced production costs due to:
  A) smaller storing costs, i.e. less locking up of capital (-10%)
  B) smaller packaging costs, due to the need to pack a single device (-20%)
  C) smaller expedition costs, for the same reason (-15%)
  D) reduced storing spaces
  E) smaller assembling costs, as more operations can be done with a high level of automation (-30%)
  F) smaller technical assistance costs (-25%)

- possibility to lower selling prices, which lead greater market share

- possibility to ask to final user smaller spaces to accommodate the new product (1 appliance instead of 3 ones): this is a key point as business premises costs are continuously increasing.

In any case we want to underline that the major savings are realised because of the greatly simplified warehouse and inventory due to the usage of standard boards using always the same components. Moreover the compact and integrated housing allowed from microelectronics, greatly simplifies the problems of shipping and delivering the equipment. (only one instead of three much more bulky and heavy set-ups).

The added value to customers can be resumed in the follows:

- The new equipment satisfies the severe EC regulations applicable to this kind of devices, including lock out of the outputs in case of limits exceeding due to either component faults or operator misuse.

- The device is able to interface to additional modules, such as PC interfaces and most of all LCD visualisation and SmartCards readers.

- Graphic interface is user friendly.

- Buying one single device including all the performances offered by three would lower the investment for the purchaser considerably.

The most interesting saving for the customer stays in the possibility to buy the complete installation with a full integration of the three original instruments.

Beyond the advantages for the final user it should be emphasized that the configurability via software of the machine constitutes a real added value to the FU and its distributors.

Our commercial strategy is toward the promotion of this specific set-up where the price to the final user is about 30% lower than the sum of the single prices of the three original instruments.

In this particular case our customer will benefit not only from the enhanced features in flexibility and programmability but also from a significant price reduction.

Other combinations with only one module (2 integrated instruments) appear also very competitive taking into account the greatly improved features.

Now we can offer to the customer the possibility to choose between many different combinations of the single modules. It means that they can buy:
μMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem

- one appliance with only the transion
- one appliance with only the linfogei
- one appliance with only the isogei
- one appliance with the combination of transion + linfogei
- one appliance with the combination of transion + isogei
- one appliance with the combination of isogei + linfogei
- one appliance with the combination of transion + linfogei + isogei

Our commercial strategy consists now in pushing customers in buying principally appliances with the combination of two or three modules.

The complete business plan for the introduction of the new product is shown in the following table and graphs:

Due to the peculiarity of the new product being made by modules, the possible future sales can be hardly estimated by comparing one by one the various existing appliance models, as each of the existing models can be inserted on the same time both on Transion and/or on Isogei and/or on Linfogei. A comparison can be made looking at a gross figure by estimating that during the first year we shall be able to reach 550 pieces, to be increased to 630 during the second year and to 750 during the third year.

In the next table the turnover figures are in percentage

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<th>Turnover with New Product Introduction (%)</th>
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</thead>
<tbody>
<tr>
<td>100</td>
<td>154</td>
</tr>
<tr>
<td>98</td>
<td>134</td>
</tr>
<tr>
<td>81</td>
<td>154</td>
</tr>
<tr>
<td>77</td>
<td>186</td>
</tr>
</tbody>
</table>

The reason for the expected sales increase stays mainly in the improved external look of the equipment and its modularity, which we expect to meet the favour of the market.

![Turnover Comparison](image-url)
If we consider a global investment of 100 kEUR (including the industrialisation costs), the previous estimations provide a very early payback period of 6 months and what is really outstanding the ROI in 5 years is more than 15 times.

It should be noticed that the ROI would be more than 7 times even if we would have to sustain a similar amount of investment in the period and this leaves a lot of room for future replications.

These figures demonstrate that this innovation represents a real breakthrough for our company giving us the opportunity to gain a very competitive position in the market.

The use of this technology will be repeated in the future by internal planning of new modules to replace other existing products and therefore be able to offer a wider range of products. CROMOGEl and DEPIGEi are the most likely candidates for introducing the newly acquired technology in the immediate future since both of them need to offer more flexibility and performance.

17. Target audience for dissemination throughout Europe

The peculiar best practice of this AE concern the following points:

- The resource allocation and the choice of work location
- The tight control of work plan
- The modular approach
- The training session for project management and microcontroller technology choice

The target audience should be all companies involved in electro-aesthetic devices, medical devices, training devices, measurement equipment, machinery tools fields (3310, 3001, 3320, 2940),

The information that can be given during the dissemination are all produced in this document except the schematics, the control model, the software and the firmware, costs and any other economic data.

Diffusion of new approach in project management and opportunity to release a complex project are precious chances for a small enterprise like us: we believe it is very important to aid enterprises to innovate their products and their technology.

In the future Vip agrees to participate in dissemination and training actions of the TTN for persuading other First Users to improve microelectronic devices.
µMESYS: Microcontroller-based Multifunction Electro-stimulation SYStem