FUSE 25788 AE Demonstrator (F.I.R.E. Project)

AE Abstract

J&S is an Italian company , with 5 employees, that designs and produces medical equipment SW & HW design for external customers

The fisiocomputer line of equipment for physical therapy (electro-therapy, laser-therapy, magneto-therapy and ultrasound-therapy), that has been in production for over six years has to be redesigned in order to introduce new and more complex capabilities, improve the functionality and ergonomics, and lower the production costs. At the time of the project start, the experience of the J&S S.R.L in the field of Electronics was based on the use of components (chip, integrated circuit) available on the electronic consumer market. The solution to the product upgrade problem was found out with the help of TTN (Consorzio Roma Ricerche) that suggested the use of the FPGA technology in substitution of all the discrete logic circuitry. Moreover the use of the VHDL methodology simplified the design phase.

The new technology allowed a better performance/cost ratio with a consequent sales increase coupled with higher product profitability. It has also to be underlined that four fisiocomputer models share the same electronics and have a common digital control unit increasing the return of the investment.

The project duration of Application Experiment was 10 months , with funding of 57KECU. The pay back period is about 36 months.

The AE is of interest for companies that work in medical instruments sector and in the health area .

1. Company name and address

J&S S.r.l.

Registered office: Via Vecchiano, 22
00139 ROMA (ITALIA)

Production site: Via di Scorticabove, 15
00156 ROMA (ITALIA)

2. Company size

Six persons are involved in the J&S activities. They are: the Managing Director and five employees. Two of these persons are involved in the microelectronics field and four have been involved in this project.

Starting from the left of the photograph reported below:
we have Mr.Michele Sirolli, our Managing Director and production office also. Then we have Mr. Oscar Adriani, the Technical Office Responsible, Quality Insurance and Project Development also. Following this description order we have Emanuele Adriani, a new technical operator, then we have Mrs.Colella,, Purchasing Office, contacts with the suppliers and book-keeping department. The second from the right is Mr. Antonio Carotenuto, our PCB designer, technical maintenance and warehouse responsible also. The last person on the right of the picture is Mr. Curzio Adriani, the marketing responsible and the commercial office also. The personnel is mainly dedicated to design and manufacturing activities.

3. Company business description

J&S has two activities : medical equipment production and SW and HW design for external customers. The first one is the most important and includes pulmonary diagnostic and physiotherapic equipment (and accessories). In the pulmonary diagnostic field is particularly important for us the PTN18 a disposable airflow to differential pressure transducer (pneumotachograph). This product is also patented by J&S in USA and Canada, and its penetration is not so large only because of the lack of an adequate commercial promotion. In the physiotherapic area J&S produces four types of equipment: electrotherapy, laser therapy, magnetic therapy and ultrasound therapy. All these have been upgraded with this A.E..

4. Markets and Competitive Position prior to the A.E.

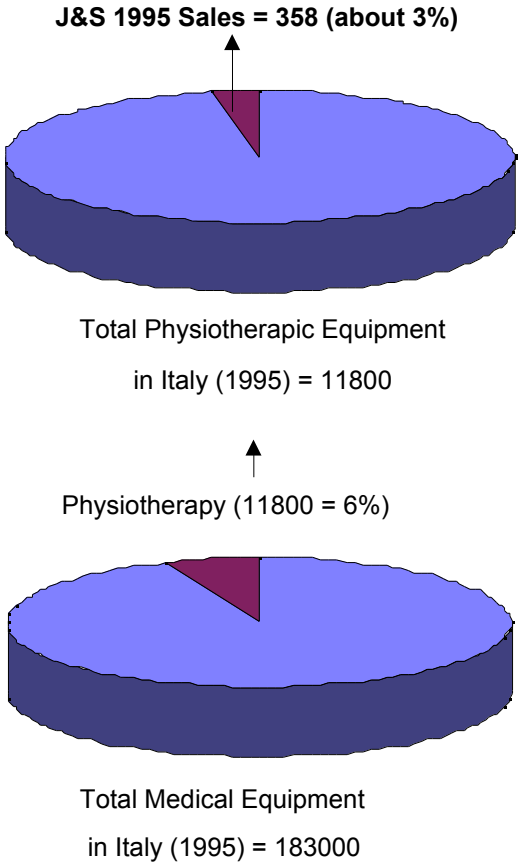
The production of physiotherapic equipment represents the 70% of our sales in the 1997(about 350 units 75% of which for the electro-theraphy segment, and the rest divided by the others. The J&S was at the time of the A.E. beginning selling this product only in the Italian market.
The total Italian market, for this type of equipment, seems to be of about 12'000 units (excluding count the aesthetic medical sector which uses similar equipment). The range of physiotherapic equipment goes from laser to magnetotherapy, from electrotherapy to ultrasound therapy in the following order of most sell products; electrotherapy 50%, magnetotherapy 20%, and the rest shared between ultrasound and laser therapy. We don't know the dimension of the EC market for these products. In Italy, however, there are many of small producers, because the type of product is too peculiar and this market does not appeal to big producers.

Most of the Italian producers aren't, from a technological point of view so advanced as one can expect, and in fact the level of the equipment is (with certain exceptions) quite low, surely not the "state of the art"!

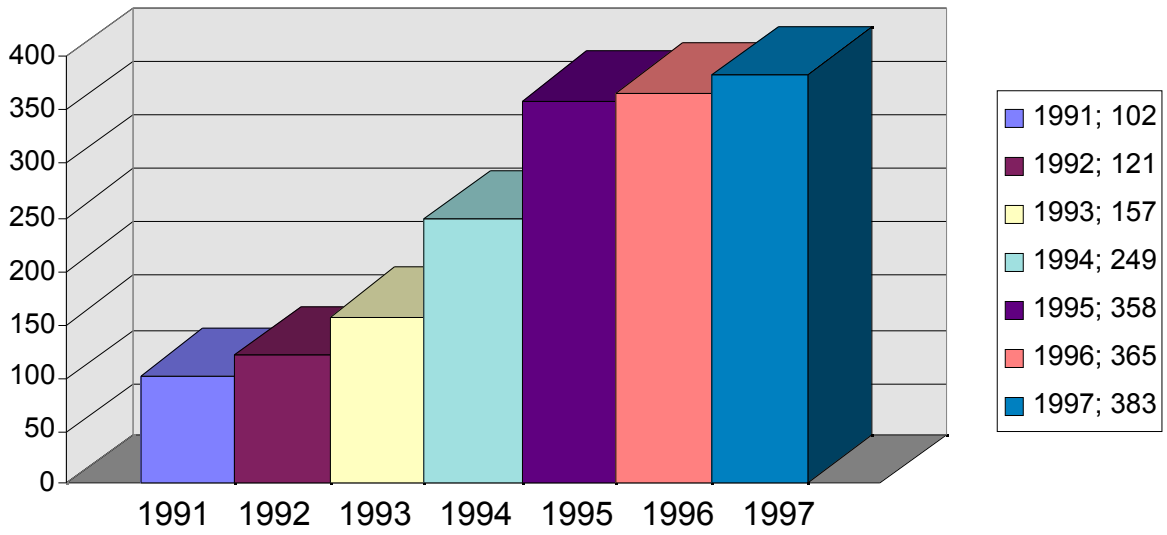
The medium price for an Electro-Therapy Equipment (having two outputs channels and the choice of the most popular current type) is situated, in Italy, between 1'000 and 3'000 ECU, depending by the offered features and the manufacturer's commercial policy.

Our "fisiocomputer ET2" (the equipment that responds to the above mentioned characteristics) is priced today at 1'200 ECU, and its industrial cost is about 300 ECU. (Note that the price for our regional distributors is 600 ECU).
The main customers of the **fisiocomputer** are private phisioterapic centres rather than public centres. One of the main market requirement was the front end aspect in order to increase use easiness for the final customer.
At the beginning of this AE our idea was to increase the features, to upgrade the front-end aspect, and to reduce the production costs of about 25% (the old equipment entered the Italian market on June 1991, seven years ago) and to simplify the maintenance of the product. The target was to reduce this cost of 50%.

Sales of medical instruments in Italy :
(in units)



J&S Sales of "fisiocomputer" from 1991 to 1997 :
(in units)



5. Product to be improved and its industrial sector :

The field of these products is the Physical Therapy (by using electrical current, or magnetic fields, or laser light, or ultra-sound mechanical energy).

The electrical current is commonly used for three objects: molecular carrying of drugs (ionophoresis), muscular stimulation, anthalgic use (Tens or Dya-Dynamic currents).

The pulsating magnetic fields create a vascularizing action which is particularly valuable in the treatment of arthrosis, muscular atrophy, contusions, etc... The alternating magnetic fields are used in treatment of arthritis, epicondylitis, etc... The combined action of the two types is highly effective in the treatment of osteoporosis, consolidation of fractures, etc...

The IR Laser stimulates the metabolism, increases haematic flow, promotes capillary and articular vaso-dilation, etc...

The "fisiocomputer" product line is completely designed by J&S. The products entered the Italian market on June 1991 (with the ET2), and the foreign market on February of 1992 (with the first fourteen ET2 being sold in France). On October 1991 the US1 (ultrasound-therapy), MG2 (magneto-therapy) and LS1 (laser-therapy) models were added to the "fisiocomputer" product line. The four models share the same electronics, having in particular a common digital control unit, so this AE relates to all of the above mentioned products. The old product is shown in the figure. The size (like of the size of this paper sheets) and the weight were not the main problem of the product (that will have the same dimensions in the new version). On the other hand the electronic upgrade allowed an increase in reliability a decrease in number of components and an increase in functionalities. The old product allows only one type of therapy at time, the new one (anSWering to the market requirements and to the competitors products) will allow apply to the patient two different therapies (that means two currents) at the same time.

The internal circuitry of every "fisiocomputer" in production can be thought as composed (excluding the power supply) by two fundamental blocks the control logic and the analog interface. Some differences in the hardware implementation for each model exist, but the entire logic control unit is a standardised building block and remains unchanged. Therefore is this common part that is the object of the present AE.

Figure 1 shows the block diagram of the ET2 (2 outputs electro-therapy), that represents the "leader" among all models (roughly 75% of the current production). Clearly shown is the galvanic separation between the two main blocks. For the other models the configuration is the same, the only differences are the number of channels and the typology of the output amplifier.

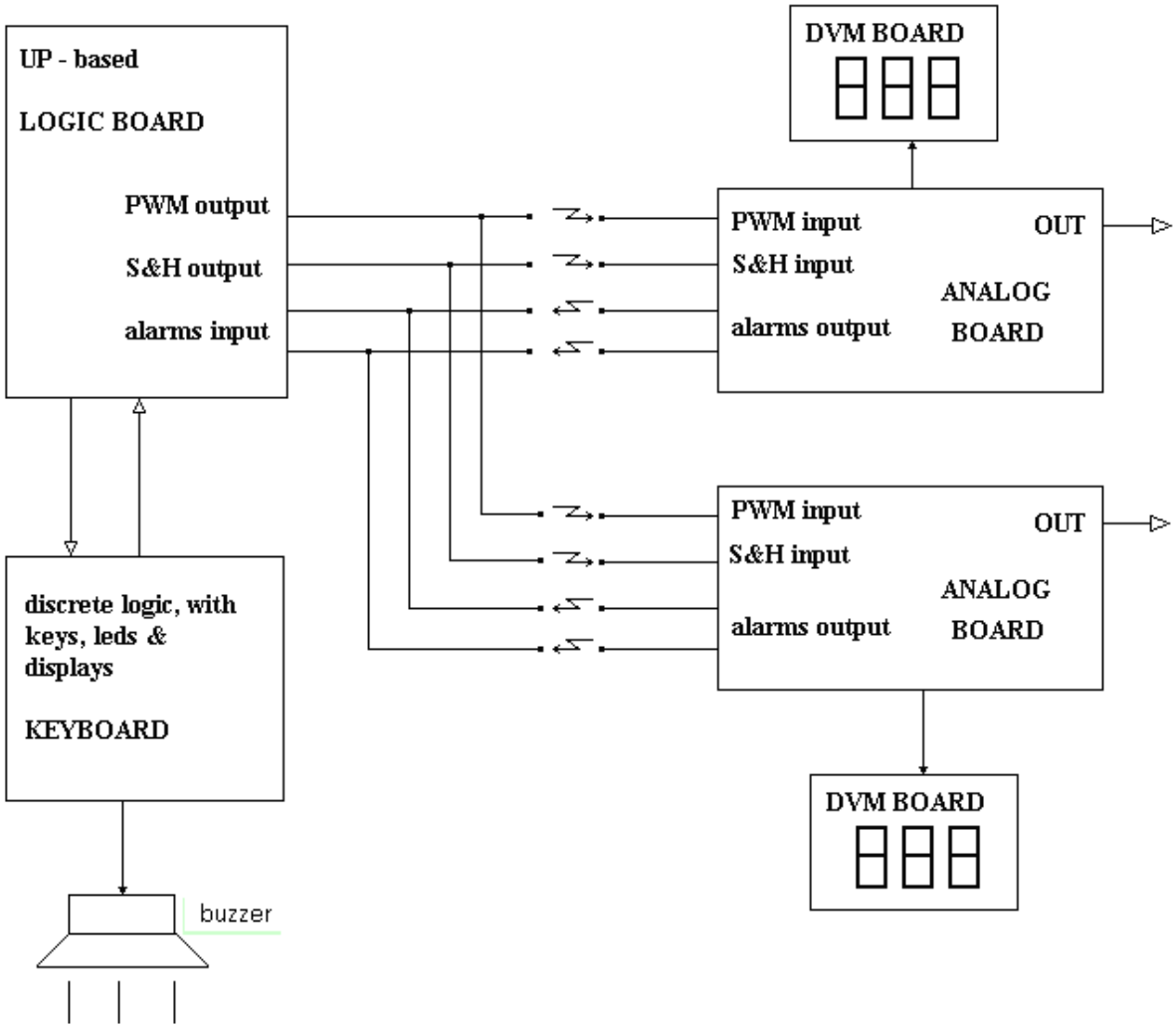
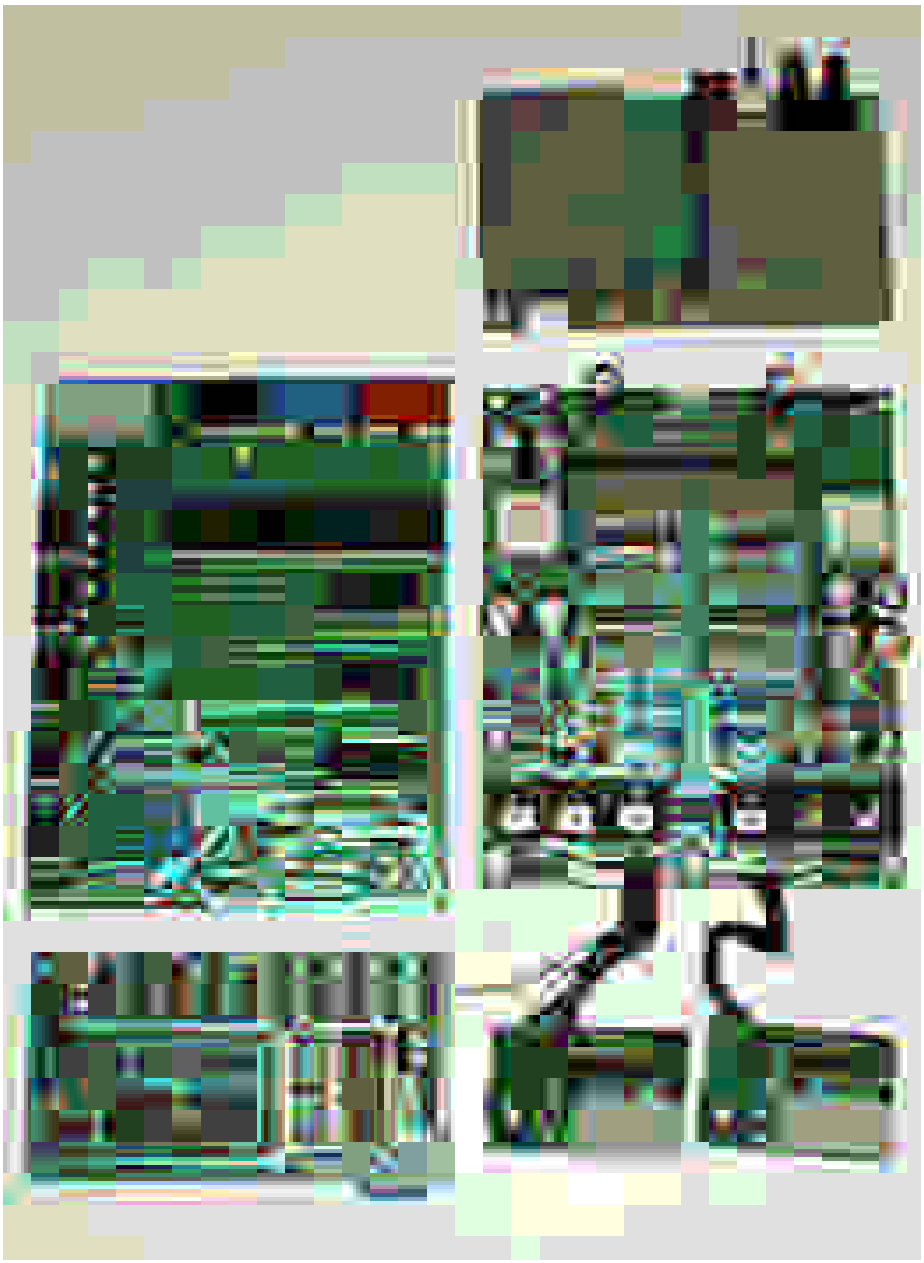


Figure 1 : Block Diagram of the old ET2

An extremely important point affecting the design and the structure of a medical piece of equipment is the security/safety of the patient. Therefore, to fully comply with the EN 60 601-1, IEC 601-2-5, IEC 601-2-10, IEC 825 and other regulations, J&S decided to galvanically insulate the logic unit from the analog part, and the analog parts to each other, in case of equipment with multiple outputs.

Obviously each of these parts must be insulated from the power mains. This fact, among other design choices, has dictated the adoption of an efficient system for the transmission of analog signals between circuit parts: the present solution uses a phase modulation PWM system, requiring only one optoisolator for each data to be transferred.



The six boards that compose the old ET2

We are defining as "logic control unit" the circuit block which controls the interface with the operator (through a keyboard, led, display, and buzzer), that is capable of interchange data with the "analog" part and, optionally, with an external Host-Computer. Figure 2 shows a more detailed block diagram of only the "logic" and the "analog" parts which are under redesign.

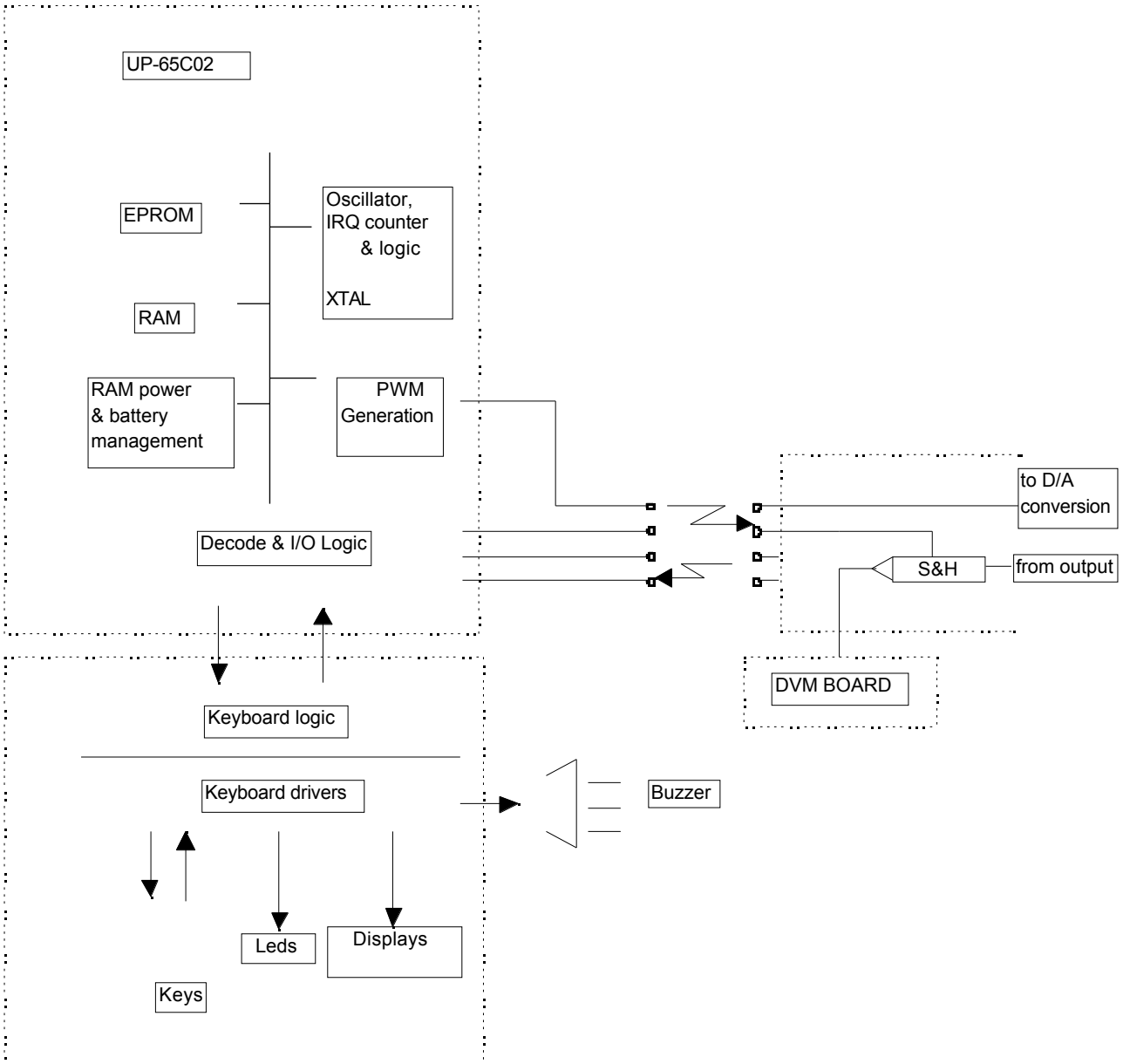


Figure 2 : more detailed block diagram for the old ET2

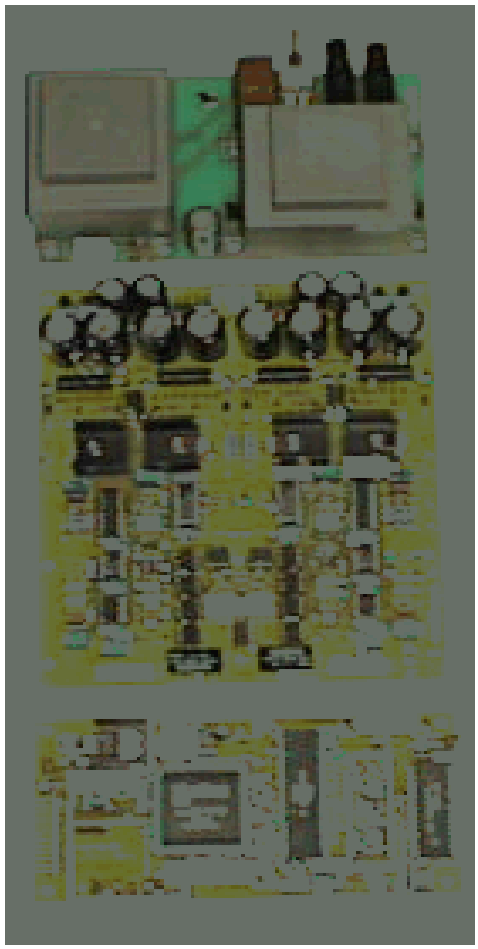
This equipment has been in production for six years (at the AE starting time), and the redesign was decided to ensure market success in the coming years and avoid decline in sales.

The main point was: to introduce new capabilities, to improve functionality and ergonomics of machines, to do all this while lowering the production costs. A better performance/cost ratio will allow a sales increase coupled with higher product profitability, and this in turn means a return of investment in a reasonable time period.

6 Description of the product technical improvements

The new Equipment has the shape than the old one, but his front-end is completely redesigned by using a membrane-keyboard and an LCD Graphic Display as shown below on the left:

The new ET2 front-end



The three boards of the new ET2

The photo on the right side shows the aspect of the (only) three boards that now compose an ET2 Equipment: the Power-Supply, the Analog Board, the Digital Board. They have the same size of the old correspondent three boards. Not more used are, on the contrary, two DVM boards and the big digital board with keys, LED's, displays (and his drivers). This reduction is mainly due to the use of FPGA device (that is the square chip on the bottom in the photo). Note that for its development we have used also the HDL language.

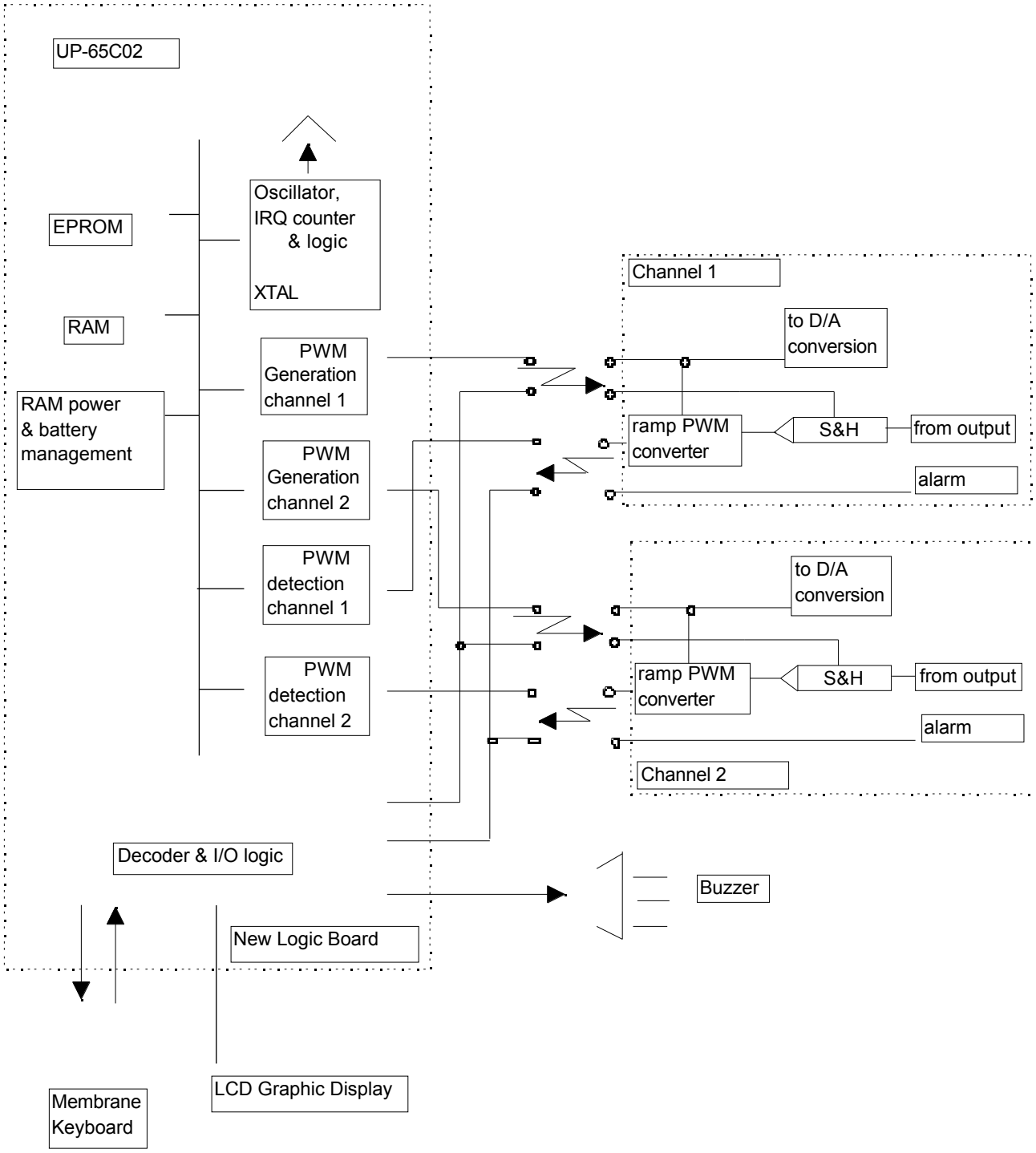


figure 3 : Block Schematic of the new ET2.

In respect to the old one, the new digital board allows the generation of two simultaneously different analog signals, the reception, from the analog board, of the output levels (and other analogic information), and obviously the driving of the LCD Graphic Display and the membrane keyboard. Also RAM and EPROM sizes have been increased.

The new digital board is based on a Lattice ispLSI1032E, which includes all the logic except microprocessor (65C02A), EPROM and RAM.

The Lattice ispLSI1032E is an High Density Programmable Logic with 6'000 PLD Gates, 64 I/O pins, 192 registers organised in 32 GLB (of 4 f/f each) and 64 f/f on the I/O pins. It presents some interesting performances like the on-board (re)programmability and the protection against undesired readings. Its use in this application is complete (100% of the 32 GLB's

Summarising the results obtained with the new technology we improved the interface between the product and the final user (use of the LCD screen), we introduced the possibility to apply two different therapies at the same time (possibility already implemented by the competitors), decreasing the number of electronic components (1 FPGA replaces more than 30 digital ICs!) we increased the easiness of the equipment maintenance of about 50%, and we decrease the production costs. Regarding the production costs, it is important to note that in respect to the forecasts, the savings in the costs of the components for the digital section are resulting lower because the underestimating of the LCD graphic display cost. On the contrary, the cost savings regarding the construction and testing phases seem to result higher than in the forecasts.

The total cost saving is of about 25% and is a very good result, particularly if we consider that the new product has better characteristics compared to the old one.

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

The following is a summary of the main technical considerations which have come out in the analysis phase of the project. These are about the necessity of insulation between circuit sections, the method used for the transmission of analog signals between isolated sections, the software choices, the choice of technology for the integration of the digital section also taking in account the need to improve the protection against duplication, the choice of an expert consultant.

The necessity for galvanic insulation between the functional blocks (logic section and analog output section) is due to the nature of the equipment. In order to respect the previously mentioned guidelines and prevent undesirable interactions among the various output circuits, we found no other solution than to make the circuits electrically floating to each other, but this raises the problem of economically solving the data transfer issue.

The one bit transmission method (fixed frequency, phase modulation) has up to this day shown itself, in our products, as the best compromise between cost and required performance. The other existing possibilities are:

- to transmit the entire binary word to the analog section and locally perform Digital to Analog conversion;
- as above, but using a serial D/A Converter, reducing the optoisolators from 9 to 3.

Both will be more expensive than the current solution, based on a SWitch and a capacitor. A third option (surely the most expensive because of the required trimming both on the production line and in the operation) would be to perform the D/A conversion at the generating side (logic section), and to transmit the analog signal with an insulating linear device. We have sufficient experience with the above mentioned coupling technology (we have used it in the past on other similar project), and we know it would be difficult to obtain a transfer linearity compatible with the needed frequency range (DC to 5'000 Hz), while keeping a low signal distortion. This would result in problems with the reproducibility of these characteristics, which is the most serious problem, and would surely lead to a more complicated and costly solution with more stability problems.

The result from the above consideration is: the simple expansion of the existing structure, as shown on block schematic (figure 3), where can be noticed the circuit complexity would increase the size and cost (of both the components and assembly), and result in a possible loss of reliability. It then seems that a change in technology is needed to reach the fundamental prerequisites: to obtain better performances while lowering the production costs.

We have divided the various hypothesis in two main sections: the use of a micro-controller, or the use of programmable logic. In both cases the purpose should be the dramatic reduction in the number of system components and the deriving reduction of the PCBs surface, the cost of assembly, testing, and that of maintenance (it has been demonstrated that the numbers of needed repairs also depends on the number of the components installed).

Between the two hypothesis, after technical and economic evaluation, it has became clearly obvious that the first option is greatly hindered by a very important reason: the software. All of our equipment currently in production are equipped with SW (Software) written in 65C02 Assembler, optimised and integrated several times in the past seven years (we have thirteen different software versions for the electro-therapy equipment).

Therefore, changing the microprocessor would mean a complete rewriting of all of the SW, and its debugging systems. This seems excessive not only in respect to pure costs. The implementation time of the redesign will be greatly lengthened, all the Know-how already available on the 65C02 (familiarity with Assembler, software and hardware simulators, debugging systems) will be lost, and above all the designers experience would be put aside, and re-created on an other processor. So, rejected the hypothesis of a microprocessor change, the microcontroller solution remains viable only if it is possible to use a device with a 65C02 "core". At present the only producers for this type of devices are Rockwell and Mitsubishi, but no device in either company's catalogue is adequate (all models have very small amount of RAM bytes, too few I/O lines, or lack in other areas which make their use inconvenient).

The second hypothesis - to maintain the 65C02 and to integrate all of the residual digital circuitry in a programmable logic, seems to be the most effective, especially considering the relatively low number of machines to be produced.

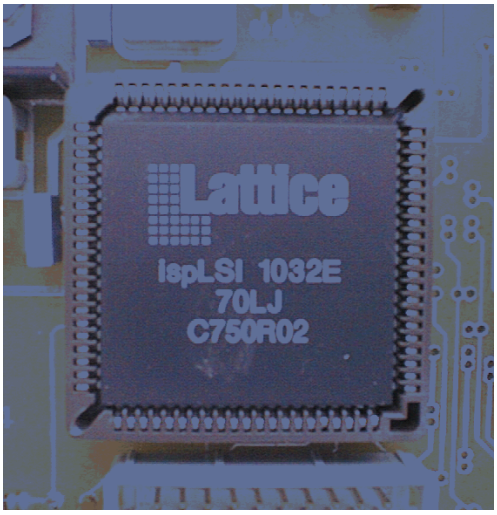
With the proper choice of the programmable logic, all the digital section has been reduced to four chips: CPU, RAM, EPROM and 1 CHIP (Lattice ispLSI1032E) to contain the residual logic. Moreover this chip allows protection against duplication which is a very important issue for J&S.

Summing up of technical considerations done with TTN :		
	Advantage	**Disadvantage**

Microcontroller/ DSP	· Very high integration level (only one chip)	· SW re-writing needed · Limited performances (not many Ram and EPROM)
ASIC	· high integration level (typical four chips) · low chip production cost	· Very high foundry costs
CPLD, FPGA	· high integration level (typical four chips) · reprogrammability (for some types)	· Chip cost not so low (as ASIC)

Technical Specifications for the FPGA used :

LATTICE mod. ispLSI1032E



- 6000 PLD GATES
- 64 I/0 Pins, Eight dedicated inputs
- 192 registers
- f max=90MHz (maximum operating frequency)
- tdp=10 ns (Propagation Delay)

The choice of Lattice is due to our market research that indicates several producers of this type of product: Actel, Altera, Atmel, Lattice, Microchip, Quicklogic, Xilinx. After several technical meetings with the Field Application Engineers of all the above mentioned companies, the choice was restricted to two: Altera and Lattice. As a result, we chose Lattice, because his architecture (register-oriented, ideal for our use), the protection against code reading, the on-board re-programmability, and least but not last, the very low cost of his "Synario" development tool.

To be able to successfully complete the project (also in a relatively short period of time), we decided to use the experience of some external consultants: STELIN Snc for the initial training and IRIS Srl for the project assistance. Without their contribution we wouldn't have completed the project in a satisfactory way.

STELIN is a small firm operating exclusively in the areas of electronic design, HW & SW advice and training courses. We know the reliability of this firm, because we used it many years ago for other electronic projects both in the telecommunication and in the clinical analysis field.

IRIS is a partner of the local TTN leaded by Consorzio Roma Ricerche. They are involved in electronic design and they have used in their projects FPGA devices made by various manufacturers (primarily in the field of digital audio).

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

J&S has two microelectronic designers, whose experience covers hardware design for system prototyping, microprocessor based system design, real time software design and implementation, operating systems design.

In the past, in addition to the internal projects, they have worked on many projects in the field of instrumentation (i.e. HW & SW for automated clinical analysis), of telecommunications (various applications for telephone systems, one of which is a device for testing telephone units and central offices - mod. TF403, that is still listed by TELECOM ITALIA), and of data processing (various systems, including a tourist information system "Touridisc" and a didactic multiuser system realised for the Second University of Rome). Currently a new physiotherapic instrumentation, named "Hyperthermia", is under development; today's in Italy there are only two other producers, and their prices are quite high (about 30 KECU).

To be able to successfully complete the project in a relatively short time (nine working months, from July, 01 1997 to April, 30 1998 including the tests both in the lab and the field), and to start the production within a short period from the time of the system redesign we decided to make use of the experience of some consultants. In fact, it would have been impossible for us to start the design phase within two months from the AE start, we would have needed at least six months.

9. Workplan

Before starting the AE, we prepared a workplane divided in five tasks, as below:

Task : 1 - Technical management
Duration :
nine months.
Objective:
- to insure that the program will be executed in the estimated time and that the cost will be within the calculated
budget.
- to guarantee the transfer of the technologies involved in the project.
Description:
Due to the strategic importance of the project the M D of J&S will act as Technical Management. The M D will verify the progress of the project (through periodic meetings). He will contact the suppliers, prepare and release all reports on the project, both internal and external.
Deliverables:
D1.1 Monthly progress report.
D1.2 Management report (trimester).
D1.3 Final report.

Task : 2 - Training
Duration :
two months.
Objective:
To have a J&S designer to acquire the skills needed for the development (HW & SW) of the chosen components. This to allow J&S to design, realise and develop FPGA chips of equal or greater complexity to the one realised for the present project in- house.
To transfer the Know-how to other J & S projects.
Description:
The first phase will consist in the training to obtain familiarity with the development system. Further training will be realised during the execution of the project (training on the job).
Milestones:
M1 End of training.
Deliverables:
D2.1 Report on training will be enclosed in the periodic progress report.

Task : 3 - Specification
Duration :
two months.
Objective:
- To define the functional specifications of the HW and SW systems.
- To supply HW and SW designers with detailed analysis of these specifications.
Description:
To define the functional specifications, J&S will co-operate with expert users, in order to define the systems requirements. Following these consultations our analysts will write the HW specifics of the digital section to be developed. They will also write a detailed SW analysis to enable our programmers to include, in the software applications, any additions or/and modifications that the new specifications will require.
Deliverables:
D3.1 Functional specifications of the new systems.

Task : 4 - FPGA design & testing.
Duration :
four months.
Objective:
Starting from the technical specifications defined in task 3, J&S will integrate all the necessary digital parts in the FPGA for the creation of the prototypes. J&S will also design the final PCB master for the digital section. J&S will also rework the SW to conform it to the new technical specifications.
Description:
Integration on FPGA, step by step, of all the designed circuitry; at every step the component created will be connected with the circuits currently in production to obtain a complete equipment on which perform our

normal production tests. Also the SW modifications will be implemented step by step to aid the verification of the HW new implementation.

Milestones:

M2 Design fixing.

Deliverables:

D4.1 FPGA HW specifications.

D4.2 SW functional description.

Task : 5 - Evaluation

Duration :

three months.

Objective:

Evaluation of the results of the redesign. Verification that all the objectives set in task 3 have been reached. Field tests of the equipment.

Description:

J&S will create some complete working prototypes of the new electro-terapy machines to be produced. After normal production tests they will be given to two certified physiotheraphy facilities to test all their functions. Final revision, in case some modifications are needed after the results of the field tests.

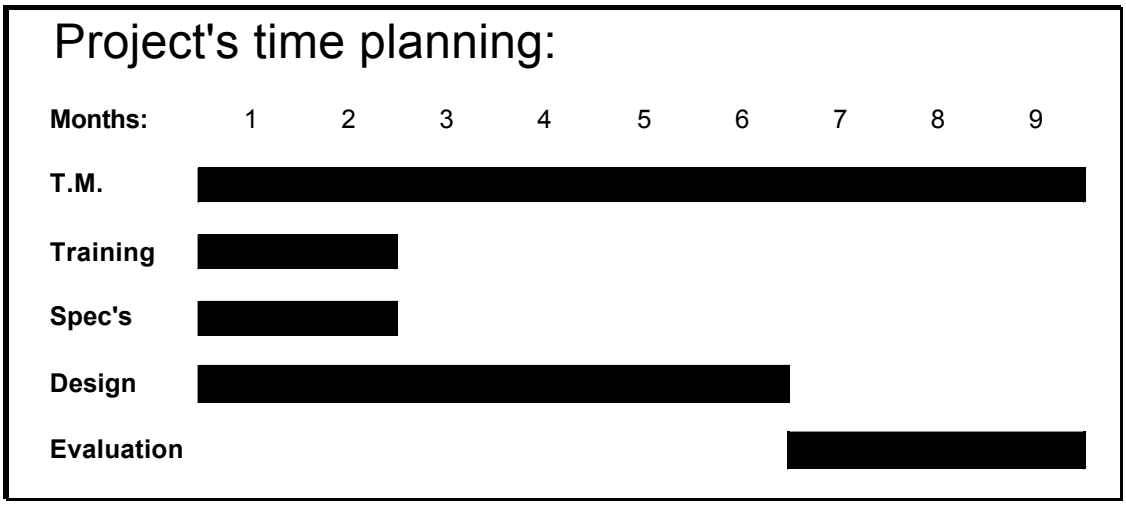
Milestones:

M3 Project conclusion.

Deliverables:

D5.1 The technical and medical reports of the new physiotherapy equipment, written by the physiotherapy facilities which carried out the field testing.

D5.2 If welcome, an electro-therapy equipment.



Risk analysis before the A.E. start: the redesign of a series of products can present the following types of risks: one technical and one economic.

The technical risk can result from failing to achieve a fully functioning product. J&S will avoid the above by making use of the Know-how of both IRIS and the certified physiotherapy facilities. Their expertise will greatly help us in the design and testing phases of all the new products. An other important asset against the above risk is also the technical expertise within J&S; and the fact that this allows J&S to shorten rapidly the times required for the various phases (which in theory could lead to the completion of the overall project in a shorter time span). J&S will take the direct responsibility for the technical management task in order to have a continuous and direct control of the operations and reduce the risk of the project.

The economic risk, could come about by overestimating the increase in sales, which could result in a belated pay back time. In its sales forecast J & S has decided not to take into account, willingly, any increase in current sales in order to start from the worst case situation.

<u>The AE execution has showed the following facts and considerations:</u>

During the execution of the project, the work was divided between the Managing Director -Michele Sirolli and the Technical Director - Oscar Adriani, the latter dealing with all the technical aspects and the external relations with both

consultants and suppliers while the M D was in charge for meeting management and reports and the J & S Quality Certification - ISO 9001 and EN 46001.

Contrarily to the project's forecasts, the training assistance was carried out by Stelin. We thought that for the training phase this change would not cause any problem, and in fact this forecast showed itself to be right. Our personnel involved in this task was the Technical Director and a technician (Antonio CAROTENUTO, internal PCB designer), who are also the persons who subsequently worked with the Synario-Lattice CAD to implement the new project.

The specifications task was carried out by ADRIANI and CAROTENUTO with the help of a third person, Paola COLELLA, who especially held the contacts with the external medical experts and with the J&S regional dealers.

The project task was entirely done by ADRIANI and CAROTENUTO. ADRIANI was of course the responsible. During this phase was also done a pre-prototype of the logic board, that was a pin to pin replacement of a board used in the currently produced "fisiocomputer ET2". This board use the Lattice ispLSI1032E instead of the previously used HCTTL gates, and a test was performed with this board on five ET2 equipment, from January, 02 1998, to test mainly the (Lattice) chip reliability in medical applications and of course the quality of our implementation!

Unfortunately we had a two-months delay in the delivery of the plastic-moulded chassis and the membrane keyboard. The only problem related to this delay was the reduction from three to one month for the on-field test for the new equipment, but this did not affect the project, because of the pre-test made in January. We used this two months supplement to improve the design , to give the finishing touch to the SW, to optimise the Lattice chip use, and for other similar uses.

Regarding the costs, they are resulted quite the same of the initial proposal because of the lower cost of the development system and the higher personnel cost in the evaluation phase. The cost of the training was quite aligned with the estimated cost, because notwithstanding the lower cost of STELIN in respect of IRIS, we decided for a greater number of lessons in this phase. The other costs of the other external assistance and the internal costs was altogether confirmed.

10.Subcontractors information

STELIN

STELIN is a small firm located in Rome, specialised, since 1989, in supplying systems and integrated technologies for Industry and Environment, like, for instance, HW & SW devices, Instrumentation, Diagnostic, Training, Research & development, concern quality. STELIN co-operates also with the Ansaldo group in the field of non-destructive tests, and the mechanical and technological tests, supplying both design services and advanced devices. The agreements with STELIN was for a fixed number (15) of full days training at our office, in a period of two months plus one full-day at our office for the technical evaluation of the final results.
Rational for choice

- Located in ROME
- Available for keeping the lessons in our office.
- Best quality/price ratio.
- Greater availability for didactics.

IRIS

We had a vary good impression, starting from the first technical meetings whit the TTN. Iris has good experience with PCB (system) and Integrated Circuit design, from the very simple PLA to FPGA, Gate Arrays and Standard Cells, with complexities ranging up to more than 100.000 equivalent gates. We collaborated from the beginning with IRIS in the definition of the project specification. Iris was selected as the natural partner to follow the project.
Serving this group and other customers given IRIS extensive experience in the area of hardware digital system design, digital audio-signal processing, real time software design and man-machine interface software.

IRIS has participated to OMI - DE/ARM project and presently is partner in OMI - IVORY project, in charge of DSP Board development.

IRIS is a specialised company, located in the suburb of Rome, whose main customer is the Bontempi-Farfisa Group, one of the largest European manufacturer of electronic and acoustic musical instruments. This gave IRIS extensive experience in the area of hardware digital system design, digital audio-signal processing, real time software design and man-machine interface software. Therefore IRIS good experience with PCB (system) and Integrated Circuit design, from the very simple PLA to FPGA, Gate Arrays and Standard Cells, with complexities ranging up to more than 100,000 equivalent gates. IRIS has participated to OMI-DE/ARM project and presently is a partner in OMI-IVORY project, in charge of DSP Board development. The agreements with IRIS was for eight full-days of project assistance: four at IRIS office, and four in our office plus one full-day at our office for the technical evaluation of the final results.

Centro di Fisioterapia

The "Centro of Fisioterapia e Ginnastica Correttiva", hereafter indicated simply as FKT, is one of the biggest physiotherapic facilities in Central Italy. It counts up to twenty-five therapists, and a turnover of six-seven hundred patients per day. Our co-operation dates back to 1979, with the project of a microprocessor-based electro-myograph (the first in Italy at that time). One must note that in this field (medical equipment) is practically impossible to develop something without the help of an expert. The agreements with FKT was for a full-day meeting, in the spec's phase, in order to obtain a Medical Report for compiling the technical specification of the new equipment. Subsequently was provided a full operative test for a period of three months for the first five electro-therapy equipment realised with the AE. Finally was provided the mentioned full day meeting for the evaluation of the results and the release of a Final Medical Report.
Rational for choice

- 25 years of experience in the phisiotherapic field.
- Remarkable dimensions (up to 700 patients/day).
- Located in Rome close to J&S (6 Km)
- Previous collaborations

11.Barriers encountered by the company when AE technology was first introduced

Notwithstanding our inclination to electronics design (both internal and for external customers), we had never thought to use programmable logics or similar devices in our projects.
Note that we use microprocessor since 1979, and perhaps we was convinced that this one should have been sufficient to all our applications.
Surely our information about FPGA or similar devices was very poor and superficial. At the time of the FUSE submission, the experience of the J&S S.R.L in the field of Electronics was based on the use of components (chip, integrated circuit) available on the electronic consumer market. The “fisiocomputer” line of equipment for physical therapy (electro-therapy, laser-therapy, magneto-therapy and ultrasound-therapy), manufactured by the J&S has been in production for over six years. The company was looking for a solution to redesigned this quite obsolete product with the introduction of new and more complex capabilities, with the improvement of the functionality and ergonomics, and with the lowering of the production costs. The first obstacle to the innovation was the lack of knowledge in the possible technological choices.
The solution to this problem was found out with the help of TTN (Consorzio Roma Ricerche) The enterprise was contacted by the TTN through its activity of proactive work by direct mailing. All the objectives of the project should have been reached with the use of the FPGA technology in substitution of all the discrete logic circuitry. Moreover the use of the VHDL methodology should have been simplified the design phase.

12.Steps taken to overcome the barriers and to improve the products

Fortunately we became acquainted with Consorzio Roma Ricerche (the TTN) on October 1996, just in the period in which we were seriously thinking to design the new version of the "fisiocomputer" products line.
It is very likely that, without this knowledge, the innovations on the equipment should have been limited to the outward appearance and the SW, with a certain increase in production cost because all the HW addition would have been done in a traditional way.

On the contrary, with Consorzio Roma Ricerche (local TTN for FUSE and other CE projects), we began to seriously consider the FPGA option for our new project. The TTN supported J&S S.R.L. in the feasibility analysis and in the proposal presentation. The big lack of knowledge in the proposed technology was initially recovered by the TTN. The TTN provided all the technical information for the proposal submission and the F.U. decided to collaborate with the TTN also during the project development. The TTN partner Iris was initially chosen as the F.U. subcontractor for the FPGA design support. During the proposal preparation, the TTN provided support not only for the proposal "formalities" but, also and mainly, providing a short but complete course on new technologies and supporting the company in the feasibility study including both technical (design, fabrication methodologies, choice of appropriate technology, etc) and marketing aspects (market analysis, business plan, etc). J&S was enthusiastic from the beginning of the new technology possibilities.

13.Knowledge and experience acquired

With this AE, in addition to our other products (the new fisiocomputer line), we have acquired the needed know-how for the use of this kind of devices (CPLD, FPGA) and now we think that all possible digital circuit may be constructed using these technologies.

This aspect is very important not only for the reduction in prices and in times of both the design and the production phases, but also for the higher reliability and for the drastic reduction of the warehouse (in our case only one Lattice component substitutes about 30 voices of logic components). As previously describe the role of the TTN as supporting team has been fundamental for the correct development of the project.
Summary of the knowledge acquired:

- Use of Synario(for Lattice)
- CPLD/FPGA circuit implementation
- HDL language
- Capability of management for a new FPGA project but also in general increased capabilities of planning of a project (business plan construction)

14.Lesson learned

Obviously, the most important aspect is the acquisition the Know-how needed to implement projects related to the FPGA technologies , integration of the digital section even with the use of the HDL language. As far as the development of the AE is concerned, the main problem was the one related to the delays (about two months) in the delivery of the plastic-moulded chassis and the membrane keyboard. These delays were mainly due to the absence of written contracts with the relative suppliers. After this experience, in fact, we advise to claim in every case precise agreement (in written form) with the external suppliers, in which must be clearly detailed the delivery terms, the responsibility, and the penalties for possible delivery delays. This is very important if the delivery terms of some part can condition the project prosecution.

At the end of this project , we think that the best time-division for this project would have been of: two months for specs and training, six months for the design and two months for the evaluation, for a total of ten months.

On the contrary, a very positive aspect was the pre-test phase decided during the course of the design task. This fact was a partial solution for the subsequent delay in the final prototype finishing. In fact we now think that it would be better to clearly provide some intermediate test steps in the initial project of this AE.
The know-how acquired with this AE will permit us to design digital equipment (or the digital section of new equipment) more quickly and less costly than in the past. Moreover our warehouse will be, for the digital section, reduced to only four active components (1032E, 65C02A, RAM, EPROM).
For example, the Hyperthermia equipment will use the same digital section and front-end generated with this AE (our Hyperthermia's name will be really "fisiocomputer IP1").

Some hints to improve the project :

- Stipulate contracts with sub-suppliers containing penalties
- Divide the test phase in 2/3 steps
- Define more accurately the management of corrective actions during the project

15. Resulting product, its industrialisation and internal replication

The industrialisation of the apparatus generated by this AE will be done in-house.

This fact will protect us against possible further delays or negative surprises in the drawing up phase for the production plans and for the needed certification.

The AE ended in April, but the production of the new devices will not be starting before September, because we require the approval, by IMQ, of the relevant technical files (CE Directive 93/42).

So far, we have completely respected the preliminary specifications of the project, both from the electronic and medical point of view.

Note that the estimated production costs explained in the previous section 6. are the results of a study done during the first generation of the production plans. Probably this data could be slightly modified in the next months, before we start the production phase.
Another important result of this project is that from now on we will be able to reuse this technology , with enormous advantages both in economic and time saving terms.

Status of industrialisation：

- Technical project : ended **30/Apr/1998**
- Technical file for IMQ : completed **30/Jun/1998**
- UNI EN ISO 9001 Obtained from IMQ
- UNI CEI EN 46001 on **28/Sep/1998**
- CE approval from IMQ foreseen not later than : **30/Oct/1998**
- Manufacturing start : **02/Nov/1998**

Internal replication of the project

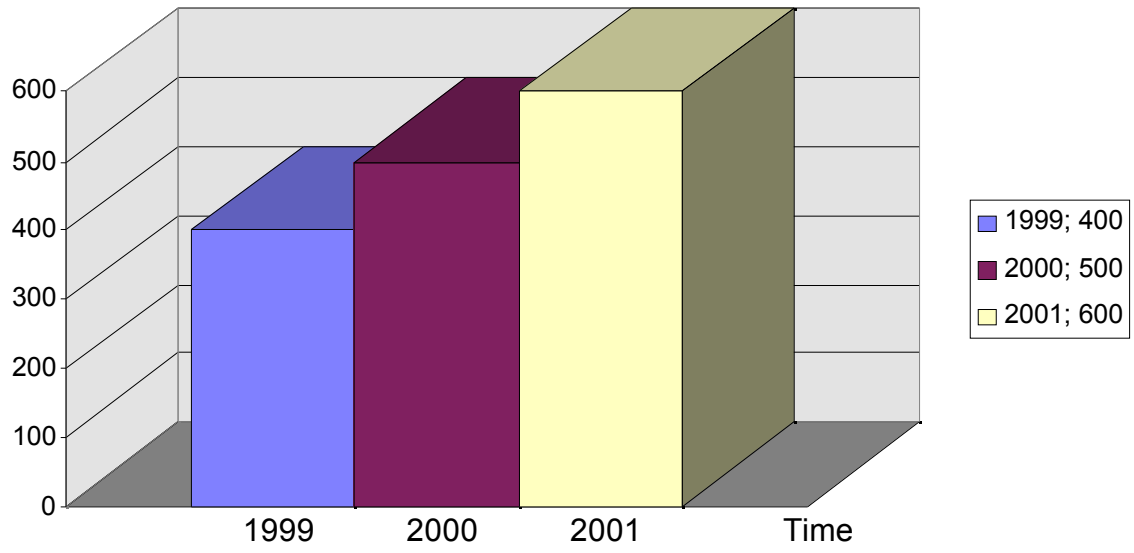
Additional advantages of the project :
Applicability of the acquired technology for all the future digital projects ;
Use of the new fisiocomputer digital board for other applications (by re-programming both HW & SW) ;
Possibility of using the some approach to similar technologies (as ASIC).

Internal : IP1 “Hyperthermia” (photo)

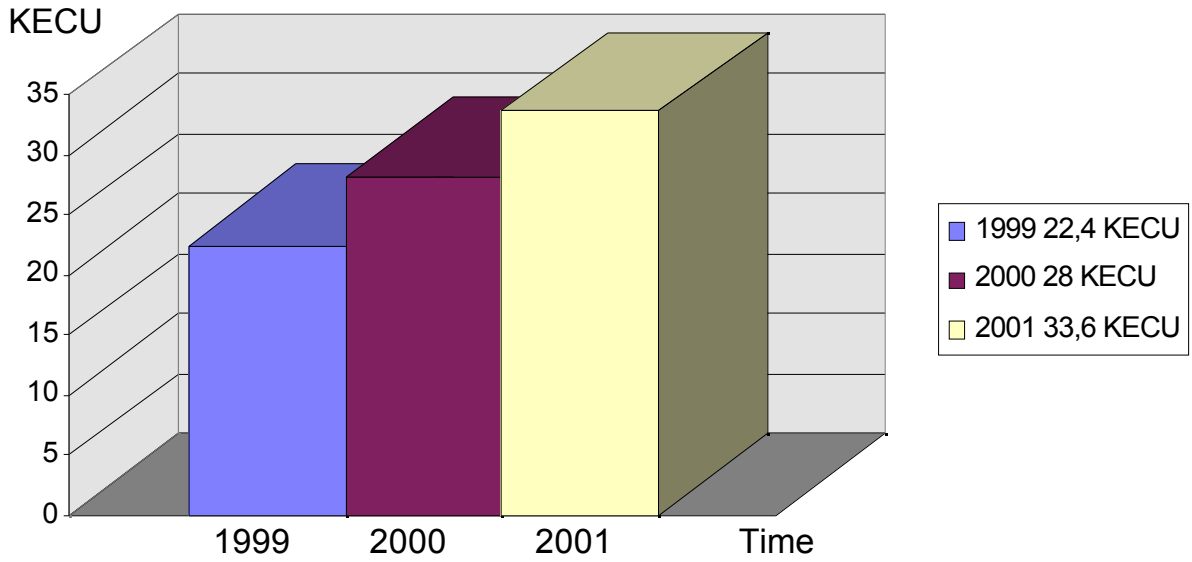
16. Economic impact and improvement in competitive position

In the last three years the sales of Fisiocomputer equipment has not changed much - 350 units per year- all of them sold in Italy.
The Italian market for this kind of equipment was, in 1995 according to the Confindustria, of 11800 units (without the esthetic medical sector).
It is difficult to compare our sales with those of our competitors because each equipment can contain multiple outlets (electrotherapy and ultrasound)
Our share of the total Italian market is 3% and one could think that thanks to the improvement of our equipment and with some good promotion one could increase the sale, but this is not our aim, our decision is to ignore this possibility estimating therefore for the next following years the same number of sold items. We have also ignored, in this phase, the additional revenues resulting from sales in other EC countries. The latter is currently under study, (in particular regarding the promotional aspects). We think our expansion in Europe could start from France and Belgium as in these two countries we are already selling other products like PTN18.
A precise evaluation has been done of the decrease in production costs that is the result of the redesigning with FPGA together with other changes introduced. This has been valued in a reduction of a 25% of the production costs, the 70% due to the implementation of FPGA and the remaining 30% to the use of other materials for the chassis. We would also like to stress the importance of the circuit simplification: while lowering the assembly and testing costs, it contributes to the improvement of product dependability.
One should also consider the predictable positive impact that this newly acquired technology has on the general design activity of our company. The use of programmable logic will be of great use in the J & S future projects helping us in implementing more complex machines more rapidly and more cost effectively.
As we have decided to maintain the same sales prices for all the “fisiocomputer” equipment, the payback period can be simply calculated considering that the sales to cover the investment - with the saving in production cost - is of about 1000 units. Obviously with the current sales rates the time needed will be of three years, but in case of increased sales, i.e. for 500 units/year, this payback period will be reduced at only two years.

Sales forecast :
(in units)



Payback period :



TOTAL SAVINGS IN 3 YEARS : 84 KEcu

Other economical advantages :

- Warehouse management for only 1 component (not more over 30 !) ;
- Important saving in the new projects of digital PCB : average design time resulted in a reduction of 50%!
- Saving in the assembly and testing phases : huge reduction due to the component integration and to the possibility to perform preliminary testing at CAD level. Average assembly and testing time has been reduced by 75%!!
- Reliability improvement: the reduced number of components and the minor complexity of PCB contributed to increase the reliability by a factor 2.

17. Target audience for dissemination throughout Europe

This A.E. can be an useful example for all the European companies belonging to industrial sectors classified with prodcome code as Medical & surgical equipment and orthopaedic appliances (33101210 prodcom code) . The target industries for dissemination has been identified mainly in sector IN (Medical instrument). The prodcom code for the target industries is 3310.
Three A.E.s resulted similar to the J&S one from the FUSE portfolio analysis.. One is another FPGA project but the product sector is completely different. The other two are similar but have been developed in other countries. The component target function is different.

At Italian local level the target industrial sector identified is the medical instrument (code 331). Most of the local enterprises belonging to this sector are small enterprises like the J&S S.r.l.. The same industrial area and the same size could be strong arguments to stimulate these enterprises (when needed) to the introduction of the FPGA technolog also at European level.
It has to be underlined that most of the companies in the targeted sector use low level electronic technologies. Only the 30% of the enterprises coded in 331 uses FPGA. The J&S S.r.l. A.E. will be utilised to stimulate a technological upgrade. Moreover the experience acquired and described in the demonstrator could be positively used as a guide to easily realise an FPGA project.
The market of the physiotherapy instruments is an increasing one as linked with the beauty care equipment one , this A.E. could be very useful to stimulate replication also in this new in fashion sector.