Biomedical Equipment Development: from Custom Circuits to Software and Building Blocks

Diego Suárez Bagnasco[1] and Franco Simini[1]

*[1]Núcleo de Ingeniería Biomédica, Instituto de Ingeniería Eléctrica,
Facultad de Ingeniería, Universidad de la República, Montevideo, Uruguay.*

Abstract— **Eleven biomedical equipment prototypes developed by Núcleo de Ingeniería Biomédica (NIB) from Universidad de la República (Uruguay) in 1987 to 2001 are reviewed. Based on interdisciplinary work of Medical School and Engineering Faculty members, the new instruments and software tools satisfy clinical and research needs in Biomedicine, and they are available for technological transfer to industry. Mean development time was 2543 man-hours (std dev=993) which accounted for 89,5% (std dev=10,5%) of total costs @ 20 USD/hour. An updated design of the projects is proposed, using present day elements, devices and development tools, yielding cost reductions in 2017 of up to 68% in materials costs, after a mean of 25 years. All prototypes developed were and some still are in clinical use, while only one of them evolved into a commercial product, confirming the one-to-ten ratio of successful investment in risk.**

Keywords— **biomedical engineering, design, education, electrical safety, prototypes.**

Resumen— **En este trabajo se hace una revisión de algunos aspectos vinculados al diseño de prototipos de equipos biomédicos desarrollados por el Núcleo de Ingeniería Biomédica (NIB) de la Universidad de la República (Uruguay) entre los años 1987 y 2001. Los equipos y el software son el resultado del trabajo interdisciplinario de miembros de la Facultad de Medicina y de la Facultad de Ingeniería y se encuentran disponibles para su transferencia tecnológica a la industria. El tiempo promedio de desarrollo fue de 2543 horas-hombre (desv est=993) las cuales representaron el 89,5% (desv est=10,5%) de los costos totales considerados @ 20USD/hora. Se propone un diseño actualizado de los prototipos, usando componentes, dispositivos y software disponible en el año 2017, lo cual arroja una reducción de costos de materiales de hasta un 68%. Todos los prototipos fueron utilizados clínicamente, y algunos de ellos aún siguen en uso. Solo un de ellos evolucionó en un producto comercial.**

Palabras clave— **ingeniería biomédica, diseño, educación, seguridad eléctrica, prototipos.**

I. INTRODUCTION

The Núcleo de Ingeniería Biomédica (NIB) is an interdisciplinary group of the School on Medicine and School of Engineering from Universidad de la República [1]. The main objectives of NIB are biomedical and clinical engineering teaching, research and technological transference to industry. NIB was created in 1985 and has evolved over the years to the present day academic structure. NIB has a functional dependence from the Department of Systems and Control, Institute of Electrical Engineering.

In 1998, the biomedical engineering profile (minor) is added to the electrical engineering (major) undergraduate career and in 2004 a biomedical engineering profile is added to the MSc in electrical engineering. Nowadays, it is also possible to apply for a PhD in electrical engineering with a biomedical engineering profile.

NIB was part of the design [2] and foundation of the Licenciatura en Ingeniería Biológica (BSc in Biological Engineering), offered since 2013 by the Departamento de Ingeniería Biológica of Centro Universitario de Paysandú (CUP), Universidad de la República. NIB is also active in outreach activities disseminating engineering and biomedical engineering in society [3] [4].

Besides scientific research and teaching, NIB activities include the development of prototypes (hardware and software applications) for biomedical research within the framework of grade, masters and doctorates degrees for physicians and engineers as well as the promotion of the national production of biomedical equipment. Since 1987, more than 30 prototypes developed by students and staff are used at the University Hospital and other state-owned hospitals in Uruguay.

Some of the most recent prototypes are [5]: PREMAX (sniff and pressure measurements for sports medicine and respiratory rehabilitation), SIMVENT (patient simulator -robot- for functional testing of mechanical ventilators), CINARTRO (image based post anterior cruciate ligament reconstruction follow up instrument), IMPETOM (electrical impedance thomography) and ADOBPRE (servo controlled abdominal pressure reduction with bladder catheter). NIB also develops several hardware and software solutions for the medical equipment industry, like the low cost phototerapy BiliLED manufactured by an uruguayan company called Controles S.A. and sold to hospitals [6]. To this end, a technology transfer contract was signed between the firm and the University. After obtaining clearance from Ministry of Health of Uruguay, the company started selling BiliLED in

2006. At present, NIB has several equipment prototypes and medical software applications to be transferred to industry for commercialization with royalty agreements.

This article presents a review and critical appraisal of the biomedical equipment developed from 1987 to 2001. The technology originally used is evaluated and an updated design is suggested, considering new elements available 20 to 30 years after.

II. Materials and Methods

This review work will consider hardware (HW) and hardware plus software (HW/SW) based prototypes, and will focus mainly on electrical and electronic related aspects. The goal of the original design was to address specific clinical needs posed by physicians of the university hospital. NIB has also developed several Medical Informatics applications, but they are excluded from the present work.

We choose to review 1987-2001 prototypes because digital and analog circuits were implemented at that time using discrete integrated circuits (IC), and printed circuit designed and built. Nowadays, many of the biomedical equipment are based in one or more microcontroller or processors. By 1974, Texas Instruments released for the electronic industry its first microcontroller called TMS100 and in 1976 Intel introduced the 8046 microcontroller. By the middle of the 90´s, microcontrollers and embedded systems became available in most countries of Latin America, and as a consequence, many of the biomedical prototypes functions and circuits could be implemented using microcontroller or using mixed analog/digital development boards.

The eleven NIB prototypes we are now revisiting were developed in 1987-2001. All NIB prototypes were used within the University Hospital (for clinical use or for research, depending on the objectives of the project).

TACONATAL 1989 [7]: neonatal heart beat acoustic tachometer. This equipment uses a condenser microphone as a transducer located in the tip of a plastic probe. It was a stand- alone device built using discrete IC for the analog and digital circuits. It could be powered from batteries or from the power network (220V, 50Hz). The equipment computed the heartbeat frequency in real time and had low, high and no frequency alarms. To reduce false alarms, TACONATAL triggers them after all three leads fail to give a measuring signal. The heart rate (HR) is somehow the result of a wired-OR, which was a completely new feature. At that time HR were obtained clinically from an ECG, with an alarm ringing whenever only ONE electrode was loose. It also had an automatic gain control. The dielectric, isolation and resistance characteristics of the internal transformer were tested to assess electrical safety aspects. The project required a total of 712 hours.

MONSE 1990 [8]: intensive care unit signal acquisition and monitoring system. MONSE was developed to acquire and process with a computer (PC, 80286 12Mhz processor) the signals from a polygraph (HP modules 8805D, 8814A, 8802A and 8811A) and a vital signs monitor (Physio control VSM5). An analog circuit was designed and connected to a standard PC card (DT2808) with a 10-bit analog to digital (A/D) and two 8 bit D/A converters. A circuit for connecting the A/D card to a X-Y register module was also developed. The PC showed up to four simultaneous signals in real time and performed offline calculations with the stored data. Circuits were built in accordance to Eurocard standards and installed in free slots inside the polygraph. Standard UNE

26011-79 [9 was considered as a framework for the electrical safety aspects of the project as well as HP´s application note AN718 [10]. The developed interface (analog circuits, PC card and PC) were powered from isolation transformers with earthed shielding. In the design, their analyzed different possible failures (earth connection failure and short circuits). All accessible metal parts of the interface were connected to earth. MONSE is a Class I equipment with protection level B. The project required 1350 hours.

VESTI 1991 [11]: Vestibular brain stem function analyzer with signal acquisition and processing. The goal of VESTI90 is the functional study of the vestibular, proprioceptive and ocular systems. Signals are input from a Berger NG-104 electronistagmograph to a PC (80286 12MHz processor and 80287 math coprocessor) using an acquisition card. VESTI90 includes a visual stimulator and a bioelectric signal amplifier to measure responses. External electrodes were used to record electronistagmogram (ENG). Standard UNE 20-613-83 [12] was considered as a framework for the electrical safety aspects of the project. VESTI is connected to the electronistagmograph and not to the patient. The electronistagmograph complies with electrical safety requirements, there is no need for special isolation for the interface. The project required 1630 hours.

VARFRE 1991 [13]: Fetal Heart Rate Variability (FHRV) and intra-uterine pressure measurement system to detect possible fetal distress. VARFRE consists of a PC, an acquisition card, transducers, and a printer. A program for signal processing was developed in C to calculate FHRV indexes with signal quality control of the acquired signals as well as FHR, fetal EKG and intra-uterine pressure. Isolated amplifiers with incorporated isolated power source (AD204JN) were used to amplify transducers signals. For the EKG signal a fetal scalp spiral electrode was used. FHR was measured using and external ultrasound transducer. The intra uterine pressure was measured using a pressure transducer and a 4mm fluid filled catheter. LM308, OP07C amplifiers were used for analog signal conditioning. An ADC acquisition board was designed to digitalize the signals (based on a ADC0808, 8-bit A/D converter with 8 multiplexed channels). From an electrical safety stand point, VARFRE relies on its isolation amplifiers. No other electrical safety considerations or essays were done. The project required a total of 3350 hours.

AUTOVENT 1992 [14]: Capnography controlled mechanical ventilation. A PC controlled interface (analog and digital circuits connected to an acquisition board) was built to acquire signals from a MSA MiniCap100 capnograph an a Drager UV1 mechanical ventilator. AUTOVENT controlled a stepper motor connected to the support pressure control knob of the ventilator. This system enabled the application of CMV and IMV+PSV ventilatory modes to the patient using a ventilator without those modes. Watch dog timer from acquisition board DT2808 was used to trigger specific control circuits that drive AUTOVENT to a secure state (mandatory frequency 16 bpm and no PSV) and make and alarm run. This safety mechanism was used to cope with possible software problems or PC failures. From an electrical safety stand point, AUTOVENT is not directly connected to the patient, and add no electrical risks. The project required 1850 hours.

FARCAR 1994 [15]: real time data acquisition and analysis of biological signals for pharmacological research. FARCAR is used to study myocardial viability in the reperfusion of ischemic myocardium. Viability was assessed

studying electrical activity, mechanical activity (diastolic and systolic pressures), metabolic activity (radioactive tracer) and perfusion pressure during a stimulus (isquemia). Isolated rat hearts were used. A PC with a four channel ISA Bus acquisition card (DAS12/50) was used to acquire signals and to control a peristaltic pump (on, off, flow, perfusion pressure measurement). The FARCAR card received the signals from an electrocardiograph machine, a polygraph with pressure transducers and a well chamber counter. FARCAR calculated peak and average values, rate of change and frequency. For signal conditioning, fourth order Butterworth filters were implemented using IC TLC04 and TLC14. The project required 2882 hours.

MONRES 1994 [16]: respiratory monitor. MONRES includes a disposable neumotacograph (Hamilton Medical 279331) and a pressure sensor that are connected at the input of an endotracheal tube as well as an esophagus pressure sensor. A mathematical model of the mechanics of the respiratory system is used during the signal processing and data analysis. MONRES calculates respiratory frequency, inspiratory and expiratory times, tidal volume, airway resistance, compliance and respiratory work. No usually seen at that time, a touch screen was used for the human-machine interface. Al the processing is done using a PC (80486DX2 66MHz) and the signals were acquired using a CDX-AD816 card of 8 analog inputs. No electrical safety tests were performed as the esophagus catheter was made of plastic -and there is normally no fluid inside it- so no electrical risks were expected. The project required a total of 3127 hours.

IMPEMAT 1996 [17]: human body electrical impedance measurement system. To be used in physician´s office and in intensive care units. IMPEMAT used a tetrapolar measurement method and could be either operated as a stand-alone equipment or connected to a PC. A set of two external electrodes (ankle and wirst) were used to inject a sinusoidal current of 1mA in the patient´s body. A XR2206 IC created a voltage signal. This voltage signal was used as the input for a voltage controlled current generator. Sinusoidal current frequency could be adjusted between 2 and 200kHz, varying resistors and capacitors values. Another set of two external electrodes was used to measure the resulting voltage in the region to be studied. A PC with a IO232 card (ITC Microcomponents) was used to control the current generator, to acquire data and to perform impedance calculations (modulus and phase). The power source had a high frequency transformer to isolate circuits from power network and optocouplers were used to isolate the PC from the rest of the system. The project required a total of 3080 hours.

CALORNAT 1997 [18]: neonatal body temperature control with display. CALORNAT had 3 skin temperature sensors (thermistors) to measure the baby's body temperature. A PC (80486DX2 66MHz, 4MB Ram) with an A/D acquisition card (CYDAS8JR) and isolated amplifiers (Analog Devices 286J) was used to measure the temperature. A heat source (electric heater or thermic mat) can be powered by CALORNAT obtaining a controlled body temperature detected by the three sensors. A solid-state relay powers the heater in order to control body´s temperature (selectable range 25.0 to 39.9 °C, accuracy +/-0.5 °C). The software was designed to avoid any possible overshoot in skin temperature. Unlike ordinary hysteresis temperature control, CALORNAT targets temperature based on previous sensor behavior. One thermistor is located in surrounding air, another is behind the baby and the third is in the line of sight of the heating element.

One of the pins of the PC´s printer port was used to control the relay (on/off control with frequency and duty cycle adjustment) and the others a set of 7 segments leds displays. A PID control was implemented in the PC control software programmed in C++. To assess electrical safety, authors applied 220V 50Hz between thermistor (patient applied part) and isolation amplifier output and registered a current of 5μA. The project required 2929 hours.

ESPECAR 1999 [19]: portable equipment for EKG acquisition and cardiac rhythm analysis with RS232 port. ESPECAR performed a 3 derivations EKG (DI, DII, DIII). The cardiac rhythm variability study was performed in a PC processing R-R signal series using autoregressive spectral estimators. A Xplor Personal Digital Controller (Blue Earth) development board was used with an Intel 8051 microcontroller (MCS-51 family), a 12-bit MAX186 ADC, isolation amplifiers ISO122P (Burr Brown), instrumentation amplifiers INA118 (Burr Brown) and a DC-DC isolated converter DCP0105DP (Burr Brown). By design, ESPECAR complies with IEC601 requirements. The project required 2929 hours.

CLASICAR 1999 [20]: classification of cardiac signals. Morphologic classification of QRS complex obtained from 24 hours recordings of EKG signals stored in EKG holter systems. CLASICAR used neuronal networks running on a PC. Non-supervised training MAT networks (multiple adaptive resonance theory) were used for morphological classification of QRS complexes. The EKG signals were stored in cassette tapes (3 derivation signals). A cassette player was used to read the tapes. The 2 channels head of the player was substituted by an auto reverse head (4 channels) to simultaneously get the 3 signals. Cassette player speed was controlled. The cassette player output was connected to a National Instruments PC-LPM16 acquisition card. The acquired signals were processed in the PC using MATLAB (QRS complex detection and morphologic classification). MIT´s EKG database was used to test the system. As this system has no connection with the patient, electrical safety aspects were not taken into account. The project required a total of 3923 hours.

Table 1 presents a summary of man-hours required for the development of each one of the eleven NIB prototypes. For this review, we classified project tasks in five categories: (i) preliminary studies and general design, (ii) circuits design, (iii) software design, (iv) mechanical design, and (v) construction and final adjustments. Reviewed projects involved 2543 ± 993 man-hours (average ± standard deviation).

Preliminary studies and general design embraces the study of the problem, studies needed to gain knowledge on specific topics and all initial design steps. Circuit design involves the work needed to design the circuits for the prototype as well as circuits testing. Software design involves the development and programming of PC based applications and firmware for microcontrollers and microprocessors. Mechanical design involves printed circuit board aspects, design of mechanical components and mechanisms as well as enclosure/housing. Prototype manufacturing, tests and adjustments are all here called 'construction and final adjustments'. The percentage distribution of man-hours between tasks of each project is presented in Figure 1. In five of the projects that involved more complex processing and calculations near 50% of the work time was dedicated to software development.

TABLE I
MAN-HOURS AND MAN-MONTHS REQUIRED FOR THE DEVELOPMENT

	Taconatal	Monse	Vesti	Autovent	Farcar	Monres	Impemat	Varfre	Calornat	Clasicar	Especar
Preliminar studies and general design	n/d	250	326	340	980	458	576	379	496	791	954
Circuits design	n/d	255	489	210	404	110	1550	345	542	334	1200
Software design	n/d	570	652	1060	698	1739	310	1016	431	1985	676
Mechanical design	n/d	45	n/d	40	238	60	44	136	1052	101	n/d
Construction / Final adjustements	n/d	230	163	200	712	760	600	1474	408	712	162
Total man-hours	712	1350	1630	1850	3032	3127	3080	3350	2929	3923	2992
Total man-months	4.5	4.5	10.2	4.5	4.5	4.5	4.5	20.9	4.5	4.5	4.5
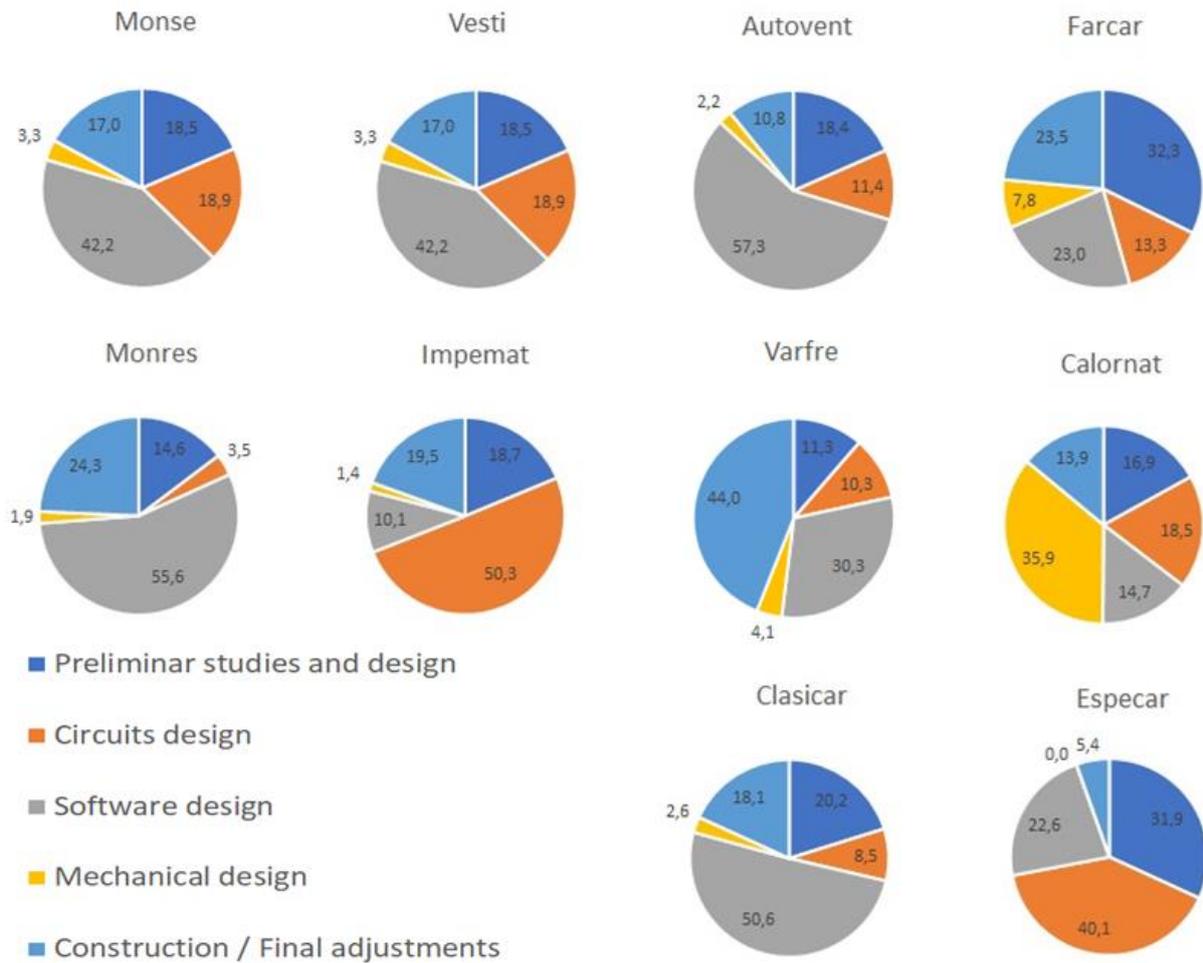
Fig. 1. Percentage of man-hour required for each task referred to the total amount of hours declared in each project memory.

On the other hand, one of the projects (IMPEMAT) had about 50% of time dedicated to circuits development and 10% for software development. This is due to the complexity of the electronics needed to implement a stand-alone biologic impedance meter (2 to 200kHz) with discrete logic gates and analog circuits.

A summary of materials and man-hour costs declared in each project is presented in Table 2. Costs of materials include the materials for each prototype and auxiliary development tools (for example, programming software packages or tools). Reviewed projects material costs ranged from U$S 216 to U$S 15.956 (U$S 4.184 ± 4.530, avg. ± std. dev.). As can be seen, human resources costs represented between 70 and 99% (89,5±10,5%) of the total cost of the projects (U$S 46.205 ± 24.369).

The man-hour costs presented in all the reviewed NIB project documentation, included engineering costs as well other costs like secretarial and administrative assistance. The available documentation does not specify if other costs (like electricity, water, office materials, etc.) were included in the reported costs.

Table 3 presents project costs pulled from each project start year to year 2017.

As the costs are expressed in U$S and most of the materials were imported (in those years mainly from USA), in an initial approximation, conversion factors were calculated using historical data of consumer price indexes from Bureau of Labor Statistics from the United States Department of Labor [21].

Now we are going to estimate year 2017 man-hours costs assuming that the same or similar project would require today the same number of man-hours (time reductions associated with better tools, equipment, etc., are discarded).

TABLE II
PROJECT COSTS DECLARED IN EACH PROJECT MEMORY (AT THE MOMENT OF DEVELOPMENT OF THE PROJECT).

	Taconatal	Monse	Vesti	Autovent	Farcar	Monres	Impemat	Varfre	Calornat	Clasicar	Especar
Project start year	1989	1990	1991	1992	1994	1994	1996	1997	1997	1999	1999
1 man/hour cost – average (U$S)	20	10	10	12	18	20	20	20	20	20	20
Project man-hour cost (U$S)	14240	13500	16300	22200	54000	62540	61600	67000	58580	78460	59840
Project cost of materials (U$S)	216	5625	5432	3850	7255	15956	682	660	2375	1760	2213
Total Project cost (U$S)	14456	19125	21732	26050	61255	78496	62282	67660	60955	80220	62053

TABLE III
ORIGINAL PROJECT COSTS PULLED TO 2017.

	Taconatal	Monse	Vesti	Autovent	Farcar	Monres	Impemat	Varfre	Calornat	Clasicar	Especar
Project start year	1989	1990	1991	1992	1994	1994	1996	1997	1997	1999	1999
Conversion factor	1,97	1,87	1,8	1,74	1,65	1,65	1,56	1,52	1,52	1,47	1,47
Project man/hour cost (U$S) to 2017	28053	25245	29340	38628	89100	103191	96096	101840	89042	115336	87965
Project cost of materials (U$S) to 2017	426	10519	9778	6699	11971	26327	1064	1003	3610	2587	3253
Total Project cost (U$S) to 2017	28478	35764	39118	45327	101071	129518	97160	102843	92652	117923	91218

TABLE IV
MAN-HOUR COSTS TAKING INTO ACCOUNT 2017 AVERAGE LOCAL SALARY.

	Taconatal	Monse	Vesti	Autovent	Farcar	Monres	Impemat	Varfre	Calornat	Clasicar	Especar
Total man-hours	712	1350	1630	1850	3032	3127	3080	3350	2929	3923	2992
Project man-hour cost 2017 (U$S)	16505	31295	37786	42886	70287	72490	71400	77659	67900	90942	69360

TABLE V
THREE MOST EXPENSIVE HARDWARE/SOFTWARE COMPONENTS OF EACH PROJECT.

Taconatal	Monse	Vesti	Autovent	Farcar	Monres	Impemat	Varfre	Calornat	Clasicar	Especar
n/d	PC U$S3925	PC and printer U$S4500	PC U$S2249	DAS12 and TICS U$S2535	PC with industrial touch screen U$S8089	n/d	Development tools (PC, Borland C, solder, oscilloscope, signal generator) U$S3500	Isolated amps U$S500	n/d	USB board U$S650
n/d	DT2808 board U$S800	DT2808 board U$S800	DT2808 board U$S850	PC U$S2024	TICS library U$S922	n/d	Integrated circuits and PCB U$S567	PC board U$S314	n/d	Local materials (misc.) U$S569
n/d	Printer U$S500	Interface board U$S52	Integrated circuits U$S310	Peristaltic pump U$S1643	Signal adapter SR03 U$S492	n/d	Local materials (misc.) U$S93	Integrated circuits U$S257	n/d	Integrated circuits U$S365

n/d: no data available

In the same way as in the reviewed projects, we will include the salaries of engineers and secretary/administrative staff in the man-hour costs, considering an average of one administrative person for each 5 engineers. Taking average 2017 values for monthly salary of a semi-senior engineer and a secretary/administrative person, hired for 40 hours of work per month as an employee in a private company in our country, we get a man-hour cost of U$S 23,2 (adding taxes and social law costs). The results for the new calculation of man-hour costs is presented in Table 4. These costs are related only to salary costs. Cost per-man per-hour may increase if we include in the calculation other work-related

costs (like consumption of energy, water, etc. per-man per-hour).

Table 5 presents the three most expensive components for each project.

It can be seen that, in those years, the cost of a PC was significate in comparison with other materials costs. The cheapest desktop PC reported had a cost of U$S 2249 in 1992. In some cases, the PC could not be substituted by other device because of the computing power needed (power achievable today with some microcontrollers, DSP, etc.). Nowadays, a generic desktop PC can be bought locally in our country for about U$S 670 (price corresponding to the following configuration: i3-7100 3,9GHz 2MB, 4GB DDR3 Ram, integrated video board Intel HD670, disk 1TB SATA 5400 rpm, 21.5'' Full HD LED monitor). Also, Table 5 shows that acquisition boards had a high price in comparison with other project materials.

III. RESULTS

Most of the NIB prototypes were based on a PC and acquisition cards and included some mixed analog/digital circuits for signal conditioning and processing. Specific printed circuit boards were designed and built for the NIB prototypes.

Nowadays several of the data processing functions implemented in those old PC´s may be achieved using for example modern microcontrollers and digital signal processors. Also, there are a huge variety of development boards available that can be used for prototyping (form Microchip, Arduino, Atmel, Texas Instruments, etc.). Those boards may include microcontroller/processor, displays, communication ports, wireless modules, FPGA, FPAA, etc. 'Development board'-based prototypes also include specific elements (like isolated power sources, isolated amplifiers, optocouplers, earthing, etc.) depending on the type and application of the biomedical equipment.

PCB area needed to for the electronic components also evolved since the first NIB project. TACONATAL (1989) used components with pin through-hole (PTH) technology. For a same integrated circuit, through-hole packages are in general bigger than SMD packages, so they require more PCB area. Depending on the complexity of the board, bigger PCB area may involve also more PCB cost. SMD components became more common in our country by the end of the 90's, as well as PCB fabrication and soldering equipment for this technology.

In many cases, the relative weight of electronic components in the total costs of a project reduced in absolute value from those years to today. Many of the electronic components are manufactured today in east Asia at lower prices than in other regions. For example, if we make an approximated cost estimation for a project like ESPECAR, considering a microcontoller based development board with Bluetooth interface, prototype casing, isolation amplifiers, etc., we get a gross local cost of materials of U$S 1030 for one prototype. The value in 1999 was U$S 2213 (or U$S 3253 pulled to 2017).

As we can see for this case, taking into account 2017 values, we get a cost reduction of electronic components of about 68% for one prototype.

After prototype evaluation, a set of test units made with custom designed and printed circuit board (PCB) and surface mount device (SMD) technology components can be manufactured. The estimated gross local cost of materials for each test unit is U$S 520. Then, serial production costs will be lower than test unit costs, but that calculation is outside the scope of this work.

Table 6 presents a comparison between prototype components and original motivation for the project and a possible 2017 implementation and project interest.

It can be seen, that in most cases, in 2017 there are several available equipment to fulfill original project requirements.

A review and improvement of some projects may have interest even today. For example, IMPEMAT project can be reviewed to improve electronics, processing algorithms and mathematical models, taking into account recent advances in mathematical models of biological electrical impedance and algorithms and actual computing processing power.

There is also place for a deeper review and improvement on electrical safety aspects.

Many different standards have been published to describe what is considered safe for the patients and operators of medical equipment (AAMI, ANSI, IEC, NFPA, OSHA, etc.). Safety testing electronic medical equipment is regarded as essential to ensure that apparatus does not pose any danger to users or patients.

To govern the design of medical equipment, the International Electrotechnical Committee (IEC) developed a type-testing standard to control safety aspects of medical equipment directly or indirectly related to the handling, use or connection. The basic standard is the IEC60601-1:2005 [22].

The first publication of IEC 60601 was done in 1977 (called IEC 601). It embraces electrical safety of both mechanical and electrical issues. Its second and third edition were published in 1988 and 2005 respectively. Complete IEC60601-1 and 60601-2 series can be found at [23].

From the standpoint of patient applied parts, two of the described prototypes have invasive sensors (MONRES: an esophagus pressure sensor, made with a plastic tube that transmits pressure to an external sensor, VARFRE: intrauterine pressure sensing using a fluid filled catether). The other prototypes involve skin electrodes or skin applied sensors.

As it can be seen in the project memories, most of the prototypes described were tested taking into account some kind of electrical safety criteria. Also, some of them were specifically designed to comply IEC electrical safety criteria (like prototype FARCAR1999).

In the reviewed time period, most of the prototypes were not tested following IEC 60601 series criteria. Despite second edition of IEC60601 was released in 1988, only one of the prototypes (MONSE) was classified from patient-applied part standpoint (as B, BF or CF) and from isolation class (I, II or III) in the project memories (that classification would determine what type of levels of isolation, insulation, creepage, clearance, and leakage would be mandated or allowed). Testing in fully accordance to 60601 requires specific equipment and experimental setups that were not available at NIB at that time.

A recent concern is the functional verification and electrical security during equipment life time (safety and efficacy) [24]. In the decade of 1990 this kind of maintenance tasks was not very common in our country. Today we can test medical equipment in accordance to several standards (for example IEC62353) [25].

TABLE VI

COMPARISON BETWEEN ORIGINAL PROTOTYPE COMPONENTS AND PROJECT INTEREST AND ACTUAL DESIGN ALTERNATIVE AND PROJECT INTEREST.

	Taconatal	Monse	Vesti	Varfre	Autovent	Farcar	Monres	Impemat	Calornat	Clasicar	Especar
Original prototype design	Condenser microphone, analog and digital ICs, power source.	PC (80286 12Mhz processor), analog circuits, aqcuisition card (DT2808) with a 10 bit analog to digital (A/D) and two 8 bit D/A converters, power source, X-Y register module.	PC (80286 12MHz processor and 80287 math coprocessor), acquisition card (DT2808), visual stimulator, bioelectric signal amplifier unit, external electrodes, power source.	PC, custom designed 8 bit A/D acquisition board, isolated amplifiers, analog ICs, transducers, power source.	PC, analog and digital circuits, acquisition board, stepper motor.	PC , acquisition card (DAS12/50), analog ICs, peristaltic pump, transucers, power source	Neumotacograph , pressure sensors, PC (80486DX2 66MHz), touch screen, acquisition board CDX-AD816 of 8 analog inputs.	External electrodes, analog and digital ICs, PC, IO232 card, high frequency isolated power source, optocouplers.	thermistors, PC (80486DX2 66MHz, 4MB Ram), acquisition board (CYDAS8JR), isolated amplifiers, heat source, solid state relay, 7 segments leds displays.	PC, cassette tapes, cassette player, auto reverse head (4 channels), National Instruments PC-LPM16 acquisition card.	Xplor Personal Digital Controller development board (Intel 8051 microcontroler), 12 bit ADC, isolation amplifiers, analog ICs, DC-DC isolated converter.
Original Interest	Neonatal heartbeat tachometer with thresholds and alarms	Acquisition of analog signals originated in intensive care unit equipment. Digital processing of the signals and plotting.	Acquisition of analog signals generated by existing electronistagmograph for posterior digital processing	Fetal cardiac frequency and intra-uterine pressure measurement system used to guide birth and to early detect acute fetal pain	Enable the application of CMV and IMV+PSV ventilatory using a ventilator without those modes	Study myocardial viability in reperfusion of isquemic myocardium (isolated rat heart)	Calculation of respiratory frequency, inspiratory and expiratory times, tidal volume, airway resistance, compliance and respiratory work.	Human body electrical impedance measurement system (standalone or PC operated)	Neonatal body temperature control	Classification of cardiac signals registered in a holter unit with casette recorder.	EKG acquisition and cardiac rhythm analysis
Actual possible alternative design (2017) for prototype	Board with microcontroller and LCD display, analog ICs, condenser microphone, medical grade isolated power source	Software application to retrieve and process data from intensive care unit equipment (using Ethernet ports)	DSP or Microprocessor board, A/D converters, isolated amplifiers, analog ICs, I/O ports, USB port, PC, external electrodes system, visual stimulator, medical grade isolated power source	DSP or Microprocessor board, A/D converters, isolated amplifiers, analog ICs, isolated communication port and PC or LCD screen/touchscreen, transducers, medical grade isolated power source	No. Most of actual available ventilators can support CMV and IMV+PSV.	PC, Board with microcontroller (A/D conv., I/O port, USB port), analog ICs, peristaltic pump, transucers, power source.	DSP or Microprocessor board, A/D converters, isolated amplifiers, analog ICs, LCD screen/touchscreen, transducers, medical grade isolated power source	DSP or Microprocessor board, A/D converters, isolated amplifiers, analog ICs, LCD screen/touchscreen, isolated communication port and PC, electrodes, medical grade isolated power source	Board with microcontroller (A/D conv., I/O port) and LCD display, isolated amplifiers, analog ICs, thermistors, optocoupled solid state relay/triac/transistor, heat source, medical grade isolated power source.	No. Acual EKG holters come with internal memory and software for EKG signals clasification	Board with microcontroller, isolated amplifiers, analog ICs, electrodes, DC-DC isolated power converter, USB port, PC.
Interest in same/similar project in 2017	Maybe. Specific features or low cost unit	Custom application to address specific signal processing and data presentation requirements	Maybe. Specific features or competitive cost unit. Actual available electronistagmography systems send data to PC for processing	Maybe. Specific features or competitive cost unit.	No. Most of actual available ventilators can support CMV and IMV+PSV.	Maybe. Lower materials cost than in original project. Additional specific features.	Many of actual available modern ventilators can calculate those parameters. Perhaps may have interest as a complement to older ventilators that cannot calculate those parameters.	Yes. Improve electronics, processing algorithms and mathematical models	Maybe. Competitive cost unit for our market (compared to other solutions in our local market).	No unless some specific useful feature can be added	Not much.

Software related issues and malfunctions were usually not considered in the 1990's. Only AUTOVENT introduces a watchdog triggered circuit to cope with possible software or PC malfunctions.

In 2017 the third release of ISO60601 is available, and requires validation for its basic design quality and thoroughness as well as its response to the unexpected or unlikely events, for any code-driven circuit or system.

Biomedical engineering development and medical equipment design and production in Latin America is generally a hard task [26]. Most of our countries do not have the economic, technical and manufacturing resources of developed countries. In some cases, it is difficult to reach even small to medium scale production and sales levels due to our internal markets size and external markets taxes and importation limitations. Also, there is a huge offer of equipment produced in east Asia at very low prices, that has penetrated many markets around the world. In this scenario, it seems that it may be better to focus and specialize in some areas of basic and applied research and in the development and design of solutions related to these areas. Doing that, we may sell high qualified services to development equipment companies in the world. From a national design and production point of view, perhaps we can focus in the design and manufacturing of some types of biomedical equipment. IMPEMAT (and its last development called IMPETOM)

may be a good example, because this kind of equipment requires a big amount of specific scientific know-how, and materials costs is only a small fraction of total costs. Most of the costs are related to human resources involved in the design and development process. In that way, as salaries in Latin America are in general much lower than in developed countries, this may be an advantage when evaluating total costs.

The prototypes developed at NIB in the analyzed period successfully met physician´s requirements. Some of them were modified or evolved in new prototypes and constituted a start-point for more ambitious projects [27].

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