

Clinical Engineering: Experiences of assisted professional practices

Luis Langone¹, Marcos Vanetta¹, Marcelo Vazquez², Viviana Rotger¹, Juan Manuel Olivera¹

¹Departamento de Bioingeniería, FACET-UNT, INSIBIO-CONICET

²Sanatorio 9 de Julio SA

PO Box 327, Zip Code (4000), Tucumán, Argentina

E-mail: bioing@herrera.unt.edu.ar

Abstract. In the curricula of the Biomedical Engineering career of the Facultad de Ciencias Exactas y Tecnología of the Universidad Nacional de Tucumán, Argentina, there are the Assisted Professional Practices. Within this framework, the students have the possibility of performing practices in the clinic Sanatorio 9 de Julio. One of the objectives of these practices is to apply the concepts, methods and procedures studied along the career in the field work under real work conditions. From the point of view of the host institution, the objective is to improve the performance of the different services and areas applying the tools of Biomedical Engineering. The present work shows an example of such practices where an equipment preliminary analysis was made, its use and maintenance corresponding to the surgical unit of the clinic.

1. Introduction

The Biomedical Engineering degree program of the Facultad de Ciencias Exactas y Tecnología (FACET) and the Universidad Nacional de Tucumán (UNT) has in its curricula the Assisted Professional Practices. These practices are in the last unit of the study plan, it has got 200 hours of classes, they are inserted within the curricula of applied technologies and it is compulsory.

The objective of the practices is to bring students into contact with the professional/working exercise doing tasks, according to the student profile, in a health institution or company (of development or construction of medical equipment).

One of the previous requirements to perform these practices is that the student has passed 34 subjects of the study plan and he/she must sign in with a coordinator, designated to that purpose, when finishing the previous unit. All the activities are done under the direct supervision of a professor, preferably of a superior course, whom will be responsible for coordinating the task that the student develops and by a tutor belonging to the institution or company.

The tutor will be responsible of writing a report evaluating the work of the student; the report will be received by a coordinator, the intern and those that the tutor considers pertinent within the scope of the institution or company. Regarding the bibliography used, as these are practices generally performed outside the academic circle, they will appeal to the existing material in the institution that welcomes the student. In most cases, it is expected that the student will be the generator of new material.

It is worth mentioning, that these practices are law N° 25.165 complaint, that creates the system of internships within the framework of what is stated in law N° 24.521 destined for superior education students of the institutions included in laws 24.195, 24.521.

In this context, an internship agreement was signed with the clinic Sanatorio Tucumán 9 de Julio. The general objective, from the point of view of host institutions, is to improve the performance of the different services and areas applying the tools of biomedical engineering.

Sanatorio 9 de Julio is a private institution dedicated to primary and secondary health care. It has an operative capacity of 155 beds. It consists of decentralized primary healthcare centres with all medical specialties. It monthly performs about 600 surgical practices, 190 children birth, 400 clinical stays and 100 short stays. These numbers correspond to 10 % healthcare of Tucuman’s population. This is performed with the coordinated work of more than 500 people [1].

Inside the institution organization there is a Clinical Engineering Department where an electronic engineer is in charge, with knowledge of biomedical and clinical engineering whom will be the tutor of the biomedical engineer interns. Among the multiple tasks developed by this department is the management of the medical technology.

In this context, it was set as an objective for the present interns to perform a preliminary analysis of the equipment, its usage and maintenance corresponding to the surgical unit of the clinic. Such an analysis will allow evaluating the frequency of maintenance, common faults, to predict preventive maintenance time and establish the rates of the devices usage.

2. MATERIALS and METHODS

The data for the present studies were obtained from a list created at the beginning of the professional practices period, between December 2006 and April 2007. The maintenance orders originated from the operating room were taken into account and from all of them only the ones pertinent to the electrosurgical generators (electro scalpel) were selected, whether it was for corrective maintenance orders or for previously tasks of preventive maintenance. All those orders that did not have an apparent justification were deleted. The list was designed using the Microsoft Excel 2000 tool, it is of internal use of the Clinical Engineering Department (DIC) and the data filled up today is: surgery date, service code that corresponds to the equipment and a brief description of the task performed, enclosing when relevant, the spare parts changed.

Figure 1 shows a partial image of the screen data

FECHA	Equipo	Mantenimiento
Servicio	COD / Serie	OBSERVACIONES
14-Dic-06	UTIP 3370	ENCENDIDO Y CONTROL DEL SENSOR
14-Dic-06	QUIROFANO F8C34184T	REPARACION Y PM
15-Dic-06	UTI UA63	Adquirida 06/05/06
15-Dic-06	UTI UA36	PM OK
15-Dic-06	UTI UA37	PM OK
15-Dic-06	UTI UA38	PM OK
15-Dic-06	UTI UA31	PM OK
18-Dic-06	NEO 390411806	PLAQUETA INTERNA
18-Dic-06	NEO 124	CABLE DE CARGADOR
21-Dic-06	UTI UA21	BATERIA - PLAQUETA - PM
21-Dic-06	UTIP 3370	CABLE ADAPTADOR PM

Figure 1. Image of the screen data: date, equipment, maintenance, service, observations, switch and sensor control

Among the directions given to interns was the analysis of technical characteristics and to obtain the users’ opinions, recommending the search of reports in different agencies as ECRI, CEDAR and those where information was available.

From this list were extracted those specific calls about the electro surgical unit which are shown in the following table.

Brand	Model	Monopolar power	Bipolar power
ValleyLab	Force 300	300 W	70 W
ValleyLab	Force 2	300 W	70 W
ValleyLab	Force 2	300 W	70 W
Minicomp	Kairos	400 W	80 W
Minicomp	Voro III	350 W	70W
Weros	Urotom	400W	80 W

The Valley Lab 300 is a microprocessor controlled device, with manual controls by rotary keys and RF isolated output, its working frequency is about 400 KHz. The manufacturer delivers it with users' manual and service. According to the 326 reports from the Medical device agency of the United Kingdom [2], it has as outstanding characteristics a good monopolar performance, well constructed, very good manuals and very good serviceability; as disadvantages the same report indicates very obtrusive audible output indicator for cut/blend (coagulation), some tissue adhesion to bipolar forceps.

The Valley Lab Force 2 is solid state, table top with an isolated RF output rated at about 500 KHz. The manufacturer delivers the users' manual. According to the 26 MDA report it is easy to use, with good performance specially for wet field work, well constructed, good access for servicing; as disadvantages it points out that some models do not comply with the 100% BS 5724 (British security rule for electro medical equipment) [3] [4]. This equipment is not registered in ANMAT but they do have the FDA approval and the CE seal.

The Minicomp Kairos is a digitally controlled device via a membrane keyboard, has an isolated floating output and the working frequency is 500 Khz. There are no ECRI or MDA reports but users notice as an advantage that is too easy to operate, the possibility of having preadjustable and recording memories and good transference; as disadvantages it has been pointed out in some isolated cases that a higher maximum cut/blend power would be preferred. This equipment is signed in ANMAT under registry N° 1363-2.

The Minicomp Voro III is a controlled device via slide potentiometers, has an isolated floating output and automatic power setting according to the impedance detected by the indifferent electrode of 2 fields. The users emphasize that it is a very compact and comfortable equipment to handle inside operation rooms. It is the preferred equipment for Urology practices and it is the precursor of KAIROS.

The Weros Urotom is a national manufacturing equipment with maximum power output of 400 W, suitable for Urology because of its high capacity of cut/blend under water. Although this equipment can be considered as "ancient" for present standards, it is used in this institution as back up. Simultaneously with the technical characteristics analysis and the users opinions, other task to perform by interns was to fill the technical form based on the "Electrosurgical preventive maintenance and inspection protocol" recommended by the electromedicine service of the Hospital Clínico Universitario Lozano Blesa, Zaragoza, España [5]. This form, adapted to local conditions, includes data belonging to the equipment such as brand and model, technical specifications, accessories (plates and electrodes), general state of the equipment (external physical state, indicators, commands, title pages, buttons, etc), alarm working. Data about the physical location of the equipment, its inventory number and the operators data are also entered. Other data that includes the form, consider some testing that at this time cannot be done quantitatively in the clinic because there is not the necessary equipment. But under ideal conditions the power tests should be done under different load condition, complete electrical security test (ground derivation current, chassis leakage, leads) and REM test [6] [7].

Although the procedures are not detailed in the list, details are entered in the technical form, the most relevant items are registered in the column "observations" in order to have a device history.

3. Results

During December 2006 and February 2007, many orders were received mainly because of problems with the Valley Force 2 sheets (indifferent electrode). The numerous faults were because of a sheet design (indifferent electrode) that was not the suitable one for the institution user's uses and habits, since it consisted of a joint cable-fixed sheet that did not endure the traction it was under daily, causing a rapid wear out of the cable in the joint area.

The Clinical Engineering Department proposed to implement a new design, changing the fixed joint for a mobile one. This renovation of sheets was done in January to the following electrosurgical units: Valley Force 2, ValleyLab Force 300, Weros Urotom and Microcomp Voro III.

Figure 2 shows the scheme of the changes performed, which were rapidly accepted by users. After the peak of demand in January 2007 no orders for this kind of fault were received, so the proposed modifications can be considered successful; no kind of problems has been reported since its change until April. The other orders responded to feed source problems or chassis wear out, besides an order for a blow in March.

Figure 3 shows how the evolution of the orders originated from the operation room was. It can be observed a decrease; this is because most of the orders were originated by faults with the indifferent electrodes.

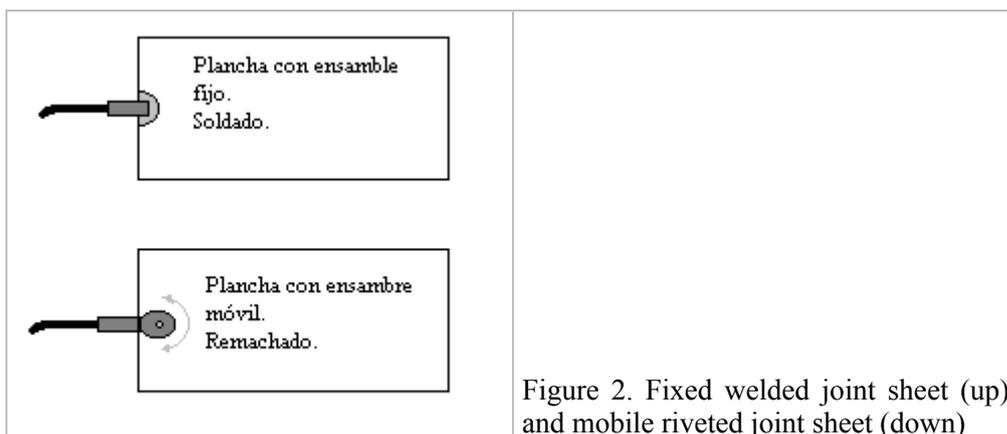


Figure 2. Fixed welded joint sheet (up) and mobile riveted joint sheet (down)

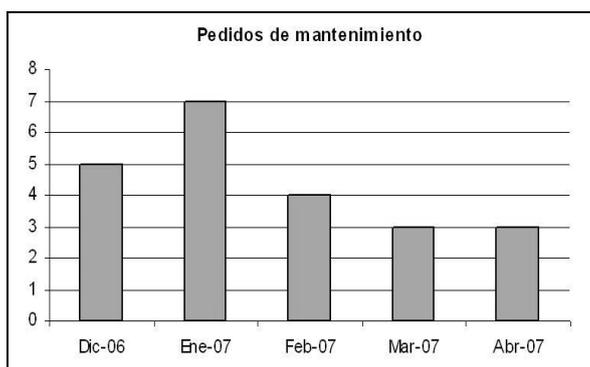


Figure 3. Number of maintenance orders originated from the surgical unit

4. DISCUSSION and CONCLUSION

Having this type of information allows to show quickly, to manage, control and report the performance and tasks done inside the Clinical Engineering Department and to point out the services that originated the orders.

Another outstanding fact is that it can be perform an exhaustive control of the orders and discriminate the own faults from faults originated for bad use of the equipment. This fact allows fixing the policies of training to improve the institutions efficiency.

Nevertheless, due to the short time passed since its implementation the data is not enough to make a statistical study, instead they allow to make a primary evaluation of the evolution in the surgery service.

By means of the application of a preventive maintenance plan and with the improvements done in the sheets design (indifferent unipolar electrodes) a 50% decrease was achieved for corrective services from the beginning of the registers. The future objective is to reach a number of calls for corrective services not superior to 2 per month.

It is important to relate this data with the average quantity of operations done daily to determine the proportions of the problems of having not programmed non working times. During 2006 an average of 24 surgeries were done daily inside the 4 operation rooms of the institution, and taking into account that we have 6 electrosurgical generators we can assure that there will always be a electrosurgical unit as backup. This fact strongly affects the efficiency index because avoids reprogramming and suspensions of surgery appointments, which can reach up to 32 daily.

5. Referencias

- [1] Sanatorio 9 de Julio SA – 25 de Mayo 372 – Tucumán – 0381-4504504
- [2] Medical Device Agency, Surgical Diathermy Units, Report N° 326. Clinical Engineering Device Assessment and Reporting, Wales. <http://www.wales.nhs.uk/sites3/home.cfm?orgid=443>.
- [3] Medical Device Agency, Surgical Diathermy Units, Report N° 26. Clinical Engineering Device Assessment and Reporting, Wales. <http://www.wales.nhs.uk/sites3/home.cfm?orgid=443>.
- [4] Medical electrical equipment. Specification for general safety requirements, BS 5724. British Standard. <http://www.bsi.org.uk>
- [5] Protocolo Mantenimiento Preventivo para Electrobisturías. Sociedad Española de Electromedicina e Ingeniería Clínica. <http://www.seeic.org>
- [6] Return Electrode Monitoring system during electrosurgical activation. Free Patents On Line. <http://www.freepatentsonline.com>
- [7] Electrosurgery Checklist. ECRI Institute's Medical Device Safety Reports (MDSR) database. <http://www.mdsr.ecri.org>

Acknowledgments

This work is supported by CIUNT (Consejo de Investigaciones de la Universidad Nacional de Tucumán) and INSIBIO (Instituto Superior de Investigaciones Biológicas) CONICET.