The need for systemic analysis and design methodology of medical equipments

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Abstract: The diversity of the medical equipments in hospital systems requires a structured analysis and design methodology in order to get perceptions and correct understandings of the internal working of these equipments. Indeed, medical equipments are intended to help the diagnosis and the medical problem treatment. They are conceived in general according to rigorous rules of security. Then, we identify various the basis types of the medical equipments: diagnosis, therapeutic, vital, monitors and laboratory equipments. To answer to this problem, the proposed methodology is based on the use of a systemic modelling approach in order to analysis and design medical equipments. This is why it is necessary to identify the rigorous security rules of various medical equipments as well as all the technical aspects related to the conception and the development of systems based on electronics and data processing.

Keywords: analysis and modelling; medical equipment; system modelling; hospital system.

Reference to this paper should be made as follows: Lakhoua, M.N. (2018) 'The need for systemic analysis and design methodology of medical equipments', *Int. J. Applied Systemic Studies*, Vol. 8, No. 1, pp.76–88.

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1 Introduction

Medical equipments represent health products and they are little or poorly known, particularly to the general public. It is difficult to give a precise definition or simply to represent what they are. However, medical equipments are an integral part of our healthcare system and they are present in a hospital system where they are found as well at the level of the patient's room to the operating block, home, ambulatory care…

In parallel, the medical equipments industry is a complex sector, due to the diversity of products and technologies implemented. The fields of application are varied and the multiplicity of equipments is at the origin of very various activities (Augusto, 2008; Chabrol et al., 2006; Soltani et al., 2018). In addition, progress over the last decade in areas such as electronics, information technology, materials, had direct consequences on the supply of care being the source of more and more sophisticated techniques. Therefore, the equipment industry saw its field of activity to expand. This sector has a strategic position within the health systems organisation and contributes to the quality of life of the patient as well as to the reduction of mortality.

Medical equipments are instruments, devices or software intended by the manufacturer to be used in humans for the purpose of diagnosis, prevention, control, treatment administration, mitigation of symptoms or care for an injury (Gourgand, 2010; Mebrek, 2008; Ben Mansour et al., 2015a).

Medical equipments are designed to help the diagnosis and treatment of medical problems. They are generally designed according to strict safety rules (Cavelery, 1994). Indeed, one can identify different types: diagnostic equipment, therapeutic equipment, vital equipment, medical monitors and medical laboratory equipment.

The complexity and the diversity of the medical equipments require a scientific methodology of analysis and the majority of the methods focus on processing information, even though it does not allow obtaining the perceptions and correct understanding of the functionality of these equipments (Jackson, 1995a; Jebali et al., 2004; Ben Salem et al., 2017). To address this problem, the proposed approach is based on the use of the systemic analysis methods in order to represent the medical equipment working.

The object of this paper consists in the proposition of a methodology of analysis and design of the medical equipments. It intends to analyse the relevance of the model achieved relatively to different functions, on the one hand and to study the technical aspects bound to the conception and the development of the medical equipment based on electronics and data processing, on the other hand.

2 Material and methods

The systemic approach, sometimes named systemic analysis, constitute a relative interdisciplinary field to the survey of objects in their complexity. It permits to fear an object of survey in its environment, in its working, in its mechanisms and in what doesn't appear while doing the sum of its parts (Vanura et al., 2010; Achachi, 2012).

In this part, first we present the case study of the medical equipment that we propose to analysis its functionality. It is about an anaesthesia respirator (DRAGER mark; FABIUS type). Second, we present the two methods objective oriented project planning (OOPP) and structured analysis and design technique (SADT).

2.1 Case study of the medical equipment

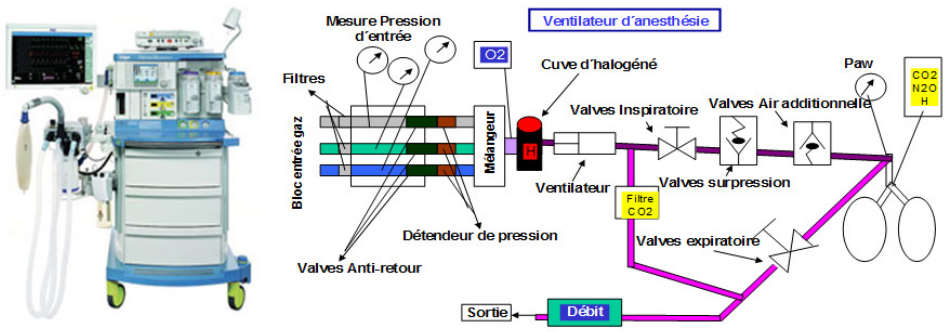
In this study, we have identified five basic types of the medical equipments:

- diagnostic equipments such as ultrasound, MRI, radiation CT scans
- therapeutic equipments such as the infusion pumps, medical lasers and surgical devices
- vital equipments used to maintain bodily functions of the patient: medical ventilator, ECMO, and dialysis device
- medical monitors that allow the medical team to measure the patient's medical condition such as ECG and EEG
- laboratory equipments such as electron microscope, operating microscope, scanning microscope.

There many facilities in surgery according to the type of the act achieved (manual DRAGER). We present few examples of facilities: respirator of anaesthesia, surgical endoscopy, electric lancet, cold light source, surgical vacuum cleaner, surveillance monitor, defibrillator, operating table, electronic insufflators, oxygen extractor, electrocardiogram…

At the time of a surgical intervention under general anaesthesia, the patient cannot breathe anymore by himself. The anaesthesia respirator (Figure 1) permits it to breathe automatic manner, while delivering the product anesthetising. This respirator is a device controlling the ventilation of the patient electronically; it delivers to the patient a composed sparkling mixture of oxygen, air and monoxide of nitrogen (gas loosening the muscular tone).

Figure 1 Principle of the anaesthesia respirator (see online version for colours)

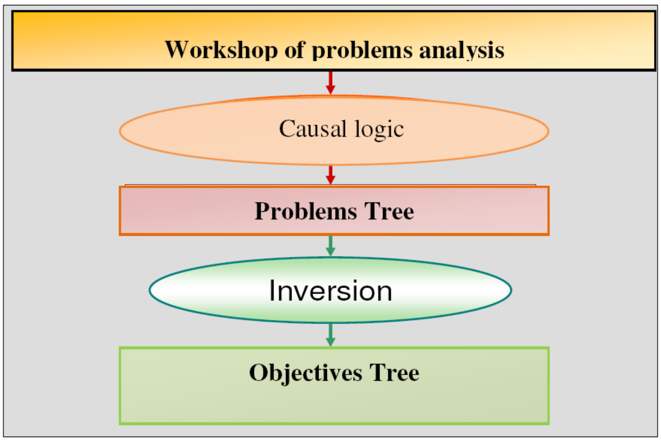


Note: DRAGER mark; FABIUS type.

2.2 *Presentation of the OOPP method*

The OOPP method which is also referred to logical framework approach (LFA) is a structured meeting process. This approach is based on four essential steps: problem analysis, objectives analysis, alternatives analysis and activities planning. It seeks to identify the major current problems using cause-effect analysis and search for the best strategy to alleviate these identified problems (AGCD, 1991; NORAD, 1999; ZOPP, 1998).

Figure 2 Presentation of the OOPP method (see online version for colours)



The first step of 'problem analysis' seeks to get consensus on the detailed aspects of the problem. The first procedure in problem analysis is brainstorming. All participants are invited to write their problem ideas on small cards. The participants may write as many cards as they wish. The participants group the cards or look for cause-effect relationship between the themes on the cards by arranging the cards to form a problem tree.

In the step of 'objectives analysis' the problem statements are converted into objective statements and if possible into an objective tree. Just as the problem tree shows cause-effect relationships, the objective tree shows means-end relationships. The means-end relationships show the means by which the project can achieve the desired ends or future desirable conditions (Annabi, 2003; Lakhoua, 2011a; Lakhoua and Ben Jouida, 2011).

The objective tree usually shows the large number of possible strategies or means-end links that could contribute to a solution to the problem. Since there will be a limit to the resources that can be applied to the project, it is necessary for the participants to examine these alternatives and select the most promising strategy. This step is called 'alternatives analysis'.

After selection of the decision criteria, these are applied in order to select one or more means-end chains to become the set of objectives that will form the project strategy (Lakhoua, 2011b, 2013; Killich and Luczak, 2002; Lakhoua, 2012).

After defining the objectives and specifying how they will be measured (objectively verifiable indicators: OVIs) and where and how that information will be found (means of verification: MOVs) we get to the detailed planning phase: 'activities planning'. We determine what activities are required to achieve each objective. It is tempting to say; always start at the situation analysis stage, and from there determine who are the stakeholders.

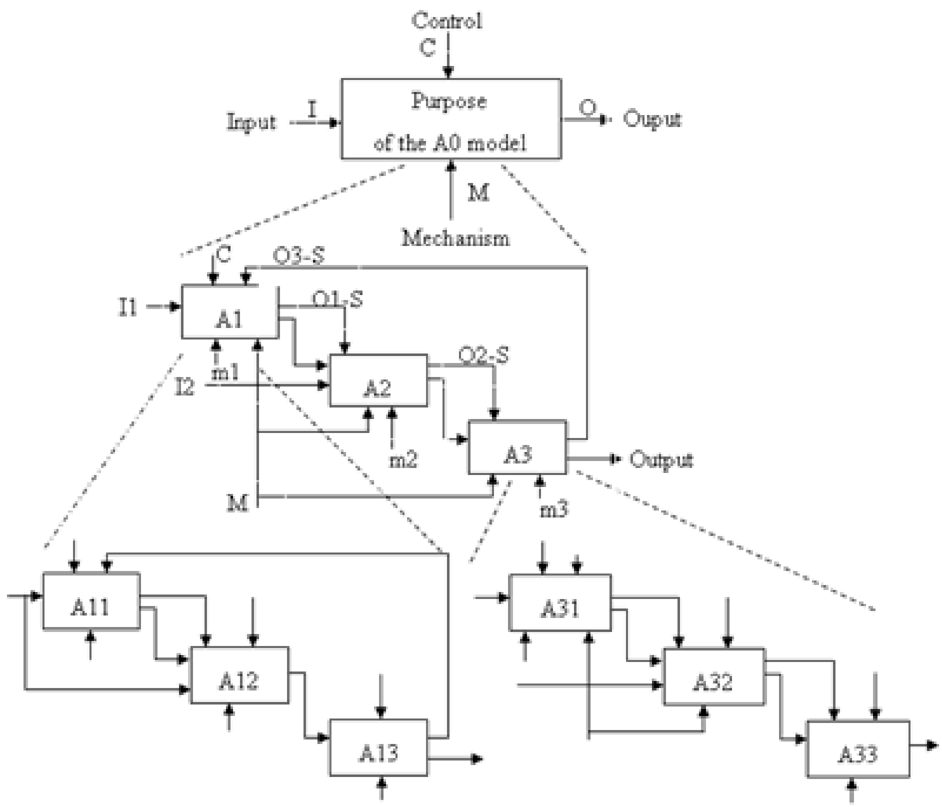
2.3 Presentation of the SADT method

The SADT method represent attempts to apply the concept of focus groups specifically to information systems planning, eliciting data from groups of stakeholders or organisational teams. SADT is characterised by the use of predetermined roles for group/team members and the use of graphically structured diagrams. It enables capturing of proposed system's functions and data flows among the functions (Jaulent, 1989; Marca and McGowan, 1988).

SADT, which was designed by Ross in the 1970s, was originally destined for software engineering but rapidly other areas of application were found, such as aeronautic, production management (Jaulent, 1992; Strohmeier and Buchs, 1996; Ben Hammouda et al., 2015)…

SADT is a standard tool used in designing computer integrated manufacturing systems, including flexible manufacturing systems. Although SADT does not need any specific supporting tools, several computer programs implementing SADT methodology have been developed. One of them is Design: IDEF, which implements IDEF0 method. SADT: IDEF0 represents activity oriented modelling approach (Schoman and Ross, 1977).

Figure 3 Top-down, modular and hierarchical decomposition of SADT method



The boxes called ICOM's input-control-output-mechanisms are hierarchically decomposed. At the top of the hierarchy, the overall purpose of the system is shown, which is then decomposed into components-subactivities.

The decomposition process continues until there is sufficient detail to serve the purpose of the model builder. SADT: IDEF0 models ensure consistency of the overall modelled system at each level of the decomposition. Unfortunately, they are static, i.e., they exclusively represent system activities and their interrelationships, but they do not show directly logical and time dependencies between them. SADT defines an activation as the way a function operates when it is 'triggered' by the arrival of some of its controls and inputs to generate some of its outputs. Thus, for any particular activation, not all possible controls and inputs are used and not all possible outputs are produced. Activation rules are made up of a box number, a unique activation identifier, preconditions and post-conditions (Peter, 2000; Peffers, 2005; Lakhoua et al., 2016).

3 Review on structured analysis methods

In this section, we present some researches on the methods OOPP and SADT in different fields. Peter (2000) has question the appropriateness of highly structured strategic planning approaches in situations of complexity and change, using the Cambodian-German Health Project as a case study. He has demonstrated the limitations of these planning processes in complex situations of high uncertainty, with little reliable information and a rapidly changing environment.

Peffers et al. (2005) have used information theory to justify the use of a method to help managers better understand what new information technology applications and features will be most valued by users and why and apply this method in a case study involving the development of financial service applications for mobile devices.

Killich et al. (2002) have presented the experiences and results of the development and implementation of a software-tool for a SME-network in the German automotive supply chain industry. The tool called TeamUp enables the communication of experts as well as the coordination of discussion groups in order to make use of synergetic potentials.

Intaek (1993) has presented the designing and the implementing the knowledge-based software assistant system for the SADT method. A graphics editor is used to create specific structured analysis (SA) diagrams and graphical symbol syntax is derived from these diagrams. First, the objective of the translator is to map a subset of the graphical symbol syntax from a SA diagram into the first order predicate calculus. The SA diagram information is represented in a set of predicate data forms. Secondly, the objective of a knowledge-based system is to evaluate adherence to proper SADT syntax. This is accomplished by generating SA rules associated with either an activity box or boundary arrows.

Rafii et al. (1994) have first presented the piloting architecture of the flexible cell and the functional analysis of the automatism by the SADT method. The piloting architecture chosen for the flexible cell of IUT of Nantes is an H-distributed one. So they have presented the fined states automates formalisation which describes the sequence and the synchronisation of the activities from the SADT decomposition. In the implementation stage, at first time, they have presented the existing centralised piloting architecture. Two original solutions are proposed for the control devices following the distributed architecture. The experimental site is a flexible cell of the IUT of Nantes.

Nowak et al. (1996) have proposed a new specification method for AMS, based on temporal SADT and deterministic/stochastic Petri nets. Temporal SADT complements conventional SADT with temporal description and additional operators leading to both dynamic and simulation SADT diagrams. Creating his own temporal SADT specification, the user can simultaneously develop its Petri net representation. At this level of specification the required calculations can be undertaken due to the mathematical PN formalism and the possibility of transforming the DSPN into a Markov graph. Such calculations allow us to detect errors and to estimate a system safety at the start of the design. Because of its structured and hierarchical formalism, the proposed method contributes to facilitating the communication between different members of the project team.

Marca (1991) have created a general framework for both systems analysis and its practice using the language-action perspective proposed by Winograd and Flores (1986). In fact, SADT, a systems analysis methodology, is augmented using this framework. This work took place on the commitment negotiation and tracking tool project. The author includes the experiences of both users and systems analysts during the project, and emphasises how to develop SADT descriptions with users to represent the richness and complexity of social interactions at work. The resulting software specification is also presented, including how it aided the work of the people who actually helped develop it.

Santarek and Buseif (1998) have described an approach to manufacturing systems design that allows automatic generation of controller logic from a high level system design specification. The high level system design specification was developed using SADT method and design: IDEF software package. The interface is based on a number of transformation rules from an IDEF0 specification into a Petri net. A standard qualitative analysis and simulation of the Petri net is used to determine if the manufacturing system will operate in the desired manner.

Moore et al. (1988) have proposed a methodology that supports reasoning in terms of functional, temporal, and resource domains. It is intended to support the complete life cycle of an avionics system. The basic SADT is augmented with a means for specifying how activities become active and for specifying timing requirements once they become active. A tool has been implemented which assists a user with the construction and verification of these temporal SADT descriptions. The result is a knowledge base amenable to temporal logic and Petri net analysis tools. The goal of the project is to demonstrate practical rooms for building verifiable real-time system designs and automated documentation. The basic temporal SADT tool has recently been complete and is being evaluated.

McGowan and Bohner (1993) have presented an approach that combines process modelling with process assessments. They use the SADT modelling notation. A SADT (IDEF0) model was created of a large software maintenance process and the model led to process improvements that might have been missed otherwise. This model based process assessment approach is described as a process in its own right

Jackson (1995b) has presented new views of mature ideas on software quality and productivity. In fact, one virtue of the SADT view of software development is its insistence on reading as well as writing the descriptions produced. In SADT, the business of reviewing what has been written is organised in the author/reader cycle. Reading is no less important in the earlier stages of development, in requirements, analysis, specification, and design, where the descriptions are-or should be-more varied both in form and in content than they are in programming.

Wright and Williams (1993) have compared five software design methodologies with respect to suitability for the design and implementation of an object-oriented process control system for the pultrusion process. Methodologies compared include: structured systems analysis and design (SSAD) with real time extensions, structured analysis and design technique (SADT), Jackson system development (JSD), object oriented design (OOD) and object modelling technique (OMT).

4 Results and discussions

After proposing to adapt a systemic approach exploiting notably the method OOPP and SADT in order to identify the various medical equipments in a hospital system, we organised many workshops which are implicating all the persons concerned by this research study. Thus, these workshops enabled us to identify not only the various medical equipments but also to make the diagnosis and to identify the various functions of an anaesthesia respirator.

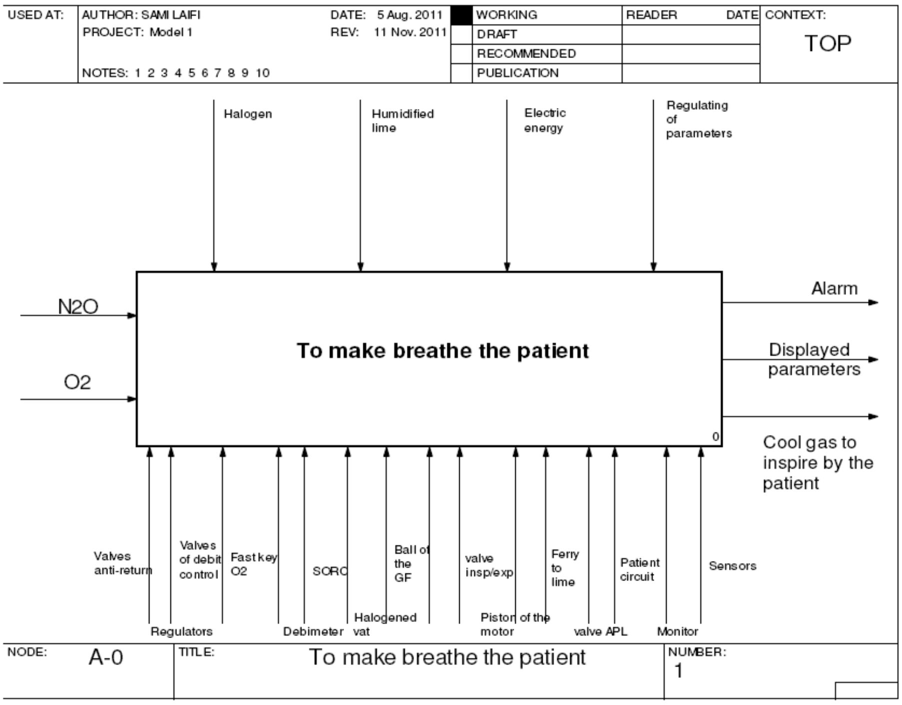
Table 1 OOPP analysis of the various medical equipments

N°	*Code*	*Designation*
1	OG	Identification of the various medical equipments assured
2	OS1	Diagnostic equipments and their components identified
3	R1.1	Components of the MRI identified
4	R1.2	Component of the ecography identified
5	R1.3	Components of the scanner identified
6	OS2	Therapeutic equipments and their components identified
7	R2.1	Components of the perfusion pump identified
8	R2.2	Components of the laser identified
9	OS3	Vital equipments and their components identified
10	R3.1	Components of the medical ventilator identified
11	R3.2	Components of the dialysis device identified
12	R3.3	Components of the ECMO identified
13	OS4	Medical monitors and their components identified
14	R4.1	Components of the electrocardiogram identified
15	R4.2	Components of the electroencephalogram identified
16	OS5	Laboratory equipments and their components identified
17	R5.1	Components of the electron microscope identified
18	R5.2	Components of the operating microscope identified
19	R5.3	Components of the scanning microscope identified

Then, during these workshops diverse validations and adjustments are done. The dedicated workshops enabled us to exploit the resource persons expertise in order to describe logically and hierarchically the diverse functions and the activities of the anaesthesia respirator.

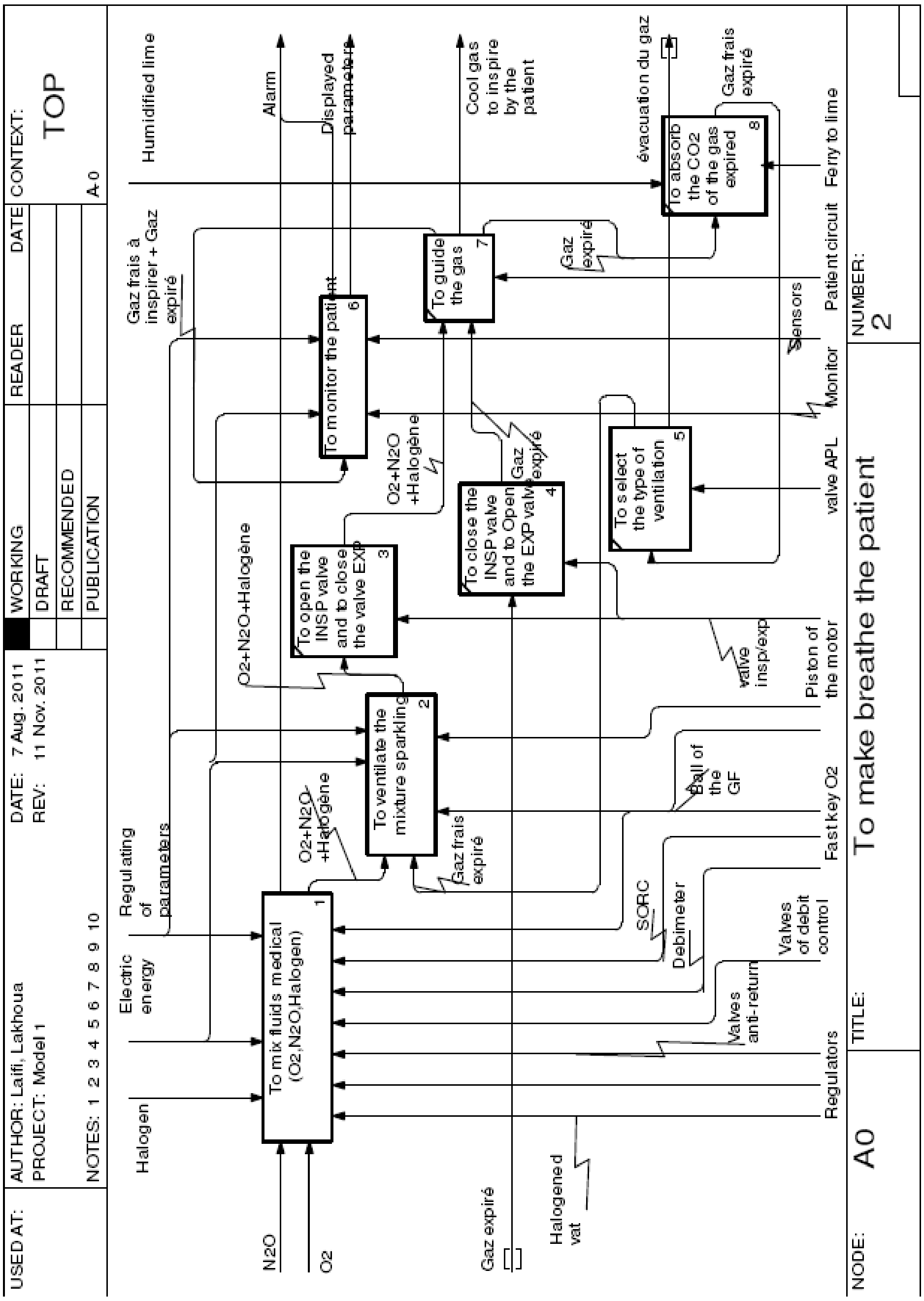
After an OOPP analysis, five specific objectives (SO) are identified corresponding to the various medical equipments (diagnostic equipments, therapeutic equipments, vital equipments, medical monitors and medical laboratory equipments). The analysis of these SO enables us to identify 13 results and more than 365 activities.

Figure 4 Node A-0 of the SADT model of the anaesthesia respirator



After analysis and modelling of the anaesthesia respirator using the SADT method, we elaborated the node A-0 (Figure 4) and the node AO (Figure 5) of the SADT model. An important point must be noticed: the point of view of the analysis is that of a person without concrete experience on the anaesthesia respirator, i.e., only through a bookish knowledge, whose objective is the use of the final model for the analysis of the surgical intervention process. Recall that the techniques such as SADT are semi-formal. By consequence, for the same subject, different correct models can be built without having to know with certitude which model is the good or, at least, the best. In fact, this kind of model allows lets users sufficient freedom in its construction and so the subjective factor introduces a supplementary dimension for its validation. That is why the validation step on the whole necessitates the confrontation of different points of views.

Figure 5 Node A0 of the SADT model of the anaesthesia respirator



5 Conclusions

In this paper, we presented a methodology of analysis of the medical equipments in a hospital system using the methods structured methods. A case study of the anaesthesia respirator was presented. In fact, the OOPP analysis enables us to identify the various medical equipments. Besides, the SADT analysis elaborated was permit to model the structure of the anaesthesia respirator. These two models are decomposed in hierarchic and structured manner and they permit to assure the effective communication between all the users of the system.

As to the OOPP and SADT methods, users can follow rules or recommendations to the level of the coherency of the models. One intends, by coherency application of the heritage rule, i.e., when data are placed at an N decomposition level, it is explicitly or implicitly present at the inferior levels. However, a complementary mean to check coherency of actigrams for the SADT model or the activities for the OOPP model is a confrontation between actigrams and datagrams or between objective tree and problem tree, which is not possible in our case.

Finally, it seems important to continue this study in order to make procedures of maintenance of this analysis and to spread the system approach to all the processes and the equipments in a hospital system, this will give the evaluation and the improvement more easy and efficient.

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