A CLINICAL ENGINEERING DECISION SUPPORT SYSTEM

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Submitted to the University of Cape Town in partial fulfilment of the requirements for the degree of

Master of Philosophy

August 1988

ACKNOWLEDGEMENTS

The author would like to make the following acknowledgements:

- to the South African Association for clinical engineering for funding the surveys
- to the Department of National Health and Population Development for permission to conduct the surveys
- to the management of Groote Schuur Hospital for the opportunity to test many of the concepts
- to my supervisor for assistance, encouragement and much needed word processing facilities
- to my wife and children for their encouragement and patience
- to my parents who, in the final analysis, made it all possible

ABSTRACT

The use of technology in health-care today is increasing dramatically with a corresponding increase in cost and complexity to provide and support it. The degree to which a hospital manages this technology affects its ability to treat patients, to perform research, to teach and to attract competent staff.

This thesis project has identified the role that clinical engineering could play in health-care technology provision and support in South Africa. A system synthesis technique was employed to develop an idealized clinical engineering model (ICE) that would satisfy South African technological requirements.

An extensive literature survey of the current status of clinical engineering in both developed and developing countries was undertaken to provide input to the synthesis process. Surveys were then conducted to determine the actual current status of clinical engineering and its environment in the RSA.

To enable such an idealised department to function as defined, it must be supported by appropriate and timeous information. The information needs of the idealised clinical engineering model were analysed and a corresponding decision support system (DSS) defined.

Further surveys were conducted to test the applicability and acceptability of the idealised clinical engineering model.

The feasibility of implementing the idealised clinical engineering model in South Africa was investigated and recommendations were made based on the research results of this thesis to bring the actual status of clinical engineering closer to the idealised model.

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LIST OF ABBREVIATIONS

AAMI	Association for the Advancement of Medical Instrumentation
ATE	Automated test equipment
Bfn	Bloemfontein
CAD	Computer aided drafting
CE	Clinical engineering
CT	Cape Town
Dbn	Durban
DHSS	Department of Health and Social Security (United Kingdom)
DKI	Deutsche Krankenhaus Institut
DSS	Decision support system
EAC	Equipment advisory committee
EC-structure	Elements and couplings structure
ECRI	Emergency Care Research Institute
equip	Equipment
FDA	Food and Drug Administration
GMP	Good manufacturing practice
IBM	International Business Machine Corporation
ICC	International Certification Commission for Clinical Engineering
ICE	Idealised clinical engineering (model or system)
IEC	International Electrotechnical Commission
IS	Independent States
ISO	International Standards Organisation
JCAH	Joint Commission for the Accreditation of Hospitals
Jhb	Johannesburg
max	maximum
min	minimum
No	number

OFS	Orange Free State
PC	Personal computer
pst	postal
Pta	Pretoria
RFP	Request for proposal
RSA	Republic of South Africa
SAACE	South African Association for Clinical Engineering
SAAAMI	Southern African Association for the Advancement of Medical Instrumentation
SABS	South African Bureau of Standards
SGS	Self Governing States
ST-structures	State trigger structures
SWA	South West Africa

CHAPTER ONE : INTRODUCTION

The objective of this thesis was to define an appropriate decision support system for clinical engineering. Such a system would consist of human, organisational and other components. It would give clinical engineering personnel support in making decisions necessary for the optimal execution of their duties.

But what is clinical engineering and why is it important for South Africa ? This introduction will give an overview of the origin and development of the clinical engineering discipline and its need for decision support.

The use of technology in health-care today is increasing dramatically with a corresponding increase in cost and complexity to provide and support it. A large hospital such as the new Groote Schuur, for example, is investing over R100 million in technology which will cost almost R10 million per annum to run and support. The degree to which a hospital manages this technology will affect its ability to treat patients, perform research, teach and to attract competent staff. If the technology is not acquired or maintained optimally it leads to unnecessary spending of the already limited, finite health-care funds - every Rand wasted will deprive someone of one Rand's worth of health-care. Furthermore it can give rise to injury, ineffective treatment or incorrect diagnoses.

Technology was introduced into medical care in a rather inconspicuous manner after World War II and it grew without anyone taking particular notice. It was only by the mid-sixties that the need for proper management of technology became apparent and the need for a new discipline was identified. In 1969 the first clinical engineering department in the U.S.A. was established by Dr. Caceres (Caceres and Zara 1977). The goal of the new discipline would be to adopt a systems approach to the task of technology management. The name clinical engineering was chosen to indicate that it was a discipline to be practised in the hospital environment and to distinguish it from biomedical engineering (see appendix K for the definitions of these two related disciplines as given by the International Certification Commission). From then clinical engineering has evolved and is today well established worldwide. Over the past two decades much has been learned of the art and science of industry, that is, technology, and its application to health-care.

Clinical engineering is a relatively new discipline in South Africa and no previous formal research had been done to determine its functions and modus operandi in the South African environment. This thesis has attempted to put technology management onto a scientific basis within the context of clinical engineering and the total health-care system in South Africa.

A model of the technology environment of hospitals has been constructed using a systems engineering approach giving rise to the concept of the idealised clinical engineering (ICE) department model. The model identifies the systems involved in health-care technology management and the associated information needs of these systems. A corresponding decision support system (DSS) is defined that will provide clinical engineering with the information support needed to manage technology optimally.

Extensive surveys were conducted to determine the characteristics of the clinical engineering environment in South Africa and to test the initial acceptability of the idealised clinical engineering (ICE) model.

In many ways a clinical engineering department is similar to a modern high technology corporation. In fact, in a large teaching hospital the clinical engineering "Corporation" can typically have an annual turnover of R10 million! It therefore shares the need to make corporate-like decisions:

- What equipment to buy?

- How to minimize running costs?

- Should a task be done in-house or contracted out?

- Should the number of personnel be increased?

and also health-care specific decisions:

- Is this technology safe?

- Should xyz equipment be upgraded or replaced?

- Does this action support the hospital mission?

In the broader context the key elements of decisions making can be represented as follows:

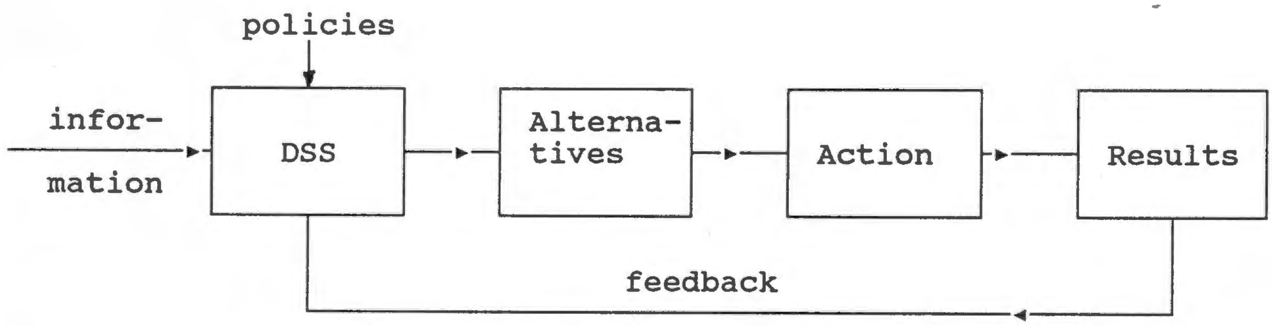

Figure 1 Elements of decision making

When an organisation is confronted with a task or problem, alternative solutions/strategies are determined. Then the best action is decided upon. The action leads to results.

The function of the decision support system (DSS) is to help formulate the alternatives and to point to the best choice. To fulfil its function a DSS requires information. The information would be relevant to the problem to be solved. The DSS process would be guided by the organisation's policies, goals and objectives as well as the infrastructure and resources available to implement the strategy decided upon.

Initial results of the action taken, are compared with the expected results. If the expected and actual results differ, the adopted strategy is amended. This feedback is an important part of the DSS process.

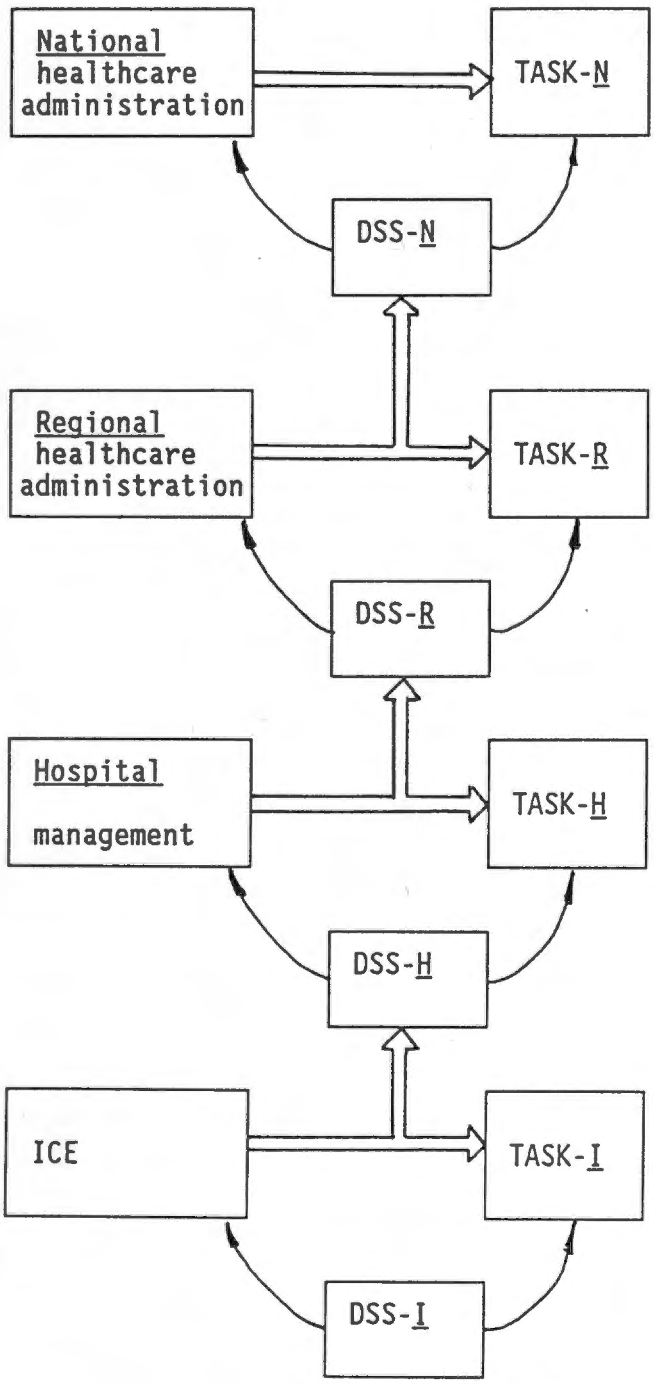

Figure 2 Vertical decomposition of clinical engineering decision support systems

Because information processing forms a major part in decision making, computers are used extensively, but not exclusively, in modern decision support systems. This thesis explores the use of computer-based decision support for clinical engineering in the RSA.

It should be borne in mind that a clinical engineering department at a hospital cannot function in isolation. The health-care technology system can typically be decomposed vertically into different hierarchical or functional levels as shown in figure 2 below.

At each level, the activities of the functional unit while executing its tasks, should provide inputs to the decision support system of the next higher level. At the same it receives guidance and direction from the higher levels. In this thesis the author concentrates on the ICE and DSS at hospital level and refers to the higher levels only to clarify the context.

CHAPTER TWO LITERATURE SURVEY

The literature survey was carried out to determine whether the concept of decision support sytems has been applied to clinical engineering and to determine the factors that would influence the application of decision support systems to clinical engineering in South Africa.

The literature survey gives insight into the many facets of clinical engineering. Although there are too many points to be listed here individually, collectively they have been incorporated into the idealised clinical engineering model presented in this thesis. Some of the more important aspects are summarised again for emphasis:

- the use of technology in health-care implies a moral and ethical commitment to also have that technology appropriately supported.
- clinical engineering is cost-effective, also in developing countries
- a systems approach is necessary if safety and costeffectiveness is to be achieved
- information is a key resource for effective clinical engineering
- developing countries have special requirements

2.1 Scope of the task

The number of different items of equipment varies according to the size and type of the hospital. For the medium sized hospital (+/- 300 beds) there would be approximately 3 000 items, and for large or teaching hospitals 6 000 to 10 000 items (Harrison, 1982, Jones, Bright and Yonovitch, 1983, Rice, McCusker and Blasingame, 1983). Scheduling preventative maintenance is an enormous task that is impossible to do manually if more than a few hundred items are involved (Loeb, 1981, Stiefel and Welker, 1981, Topham, 1979). The keeping of maintenance history records can amount to mountains of information. (Ben-Zvi,1983).

2.2 Hardware

The full spectrum of hardware possibilities is encountered in the literature. Where the hospital is small (1 000 items) or the system limited in scope to, for example, only preventative maintenance scheduling, a small microcomputer is used. (Aichinger and Kempf 1982, Fannin, Weed and Taylor, 1982, Jones, Bright and Yonovitch, 1983, Rice, McCusker and Blasingame, 1983). Most hospitals use mini or mainframe systems with the DEC PDP11 series being the most popular (Hack, Goble, Memoli, Stott and Krug, 1983, Katz and Buckley, 1981, Kresch, Hammarman and Schwartz, 1983, Loeb, 1981, Maloney, Mead and Leany, 1982, Tackel, 1981). Timesharing and rental are sometimes employed. e.g. office business computer (Harrison, 1982), hospital information system mainframe (Darnel, 1982), bureau (Maloney, Mead and Leany, 1982). Mass storage devices range from five and a quarter inch floppy discs (Aichinger and Kempf 1982, Jones, Bright and Yonovitch, 1983) to hard discs of 50 to 100 MBytes (Katz, McLun and Buckley, 1981, Kresch, Hammarman and Schwartz, 1983, Maloney and Mead, 1982, Tackel, 1981). Today local area networks are becoming more popular (Dickey 1987, Secunda 1987 (b), Du Toit 1988).

2.3 Software

In most cases standard commercial data base management systems are used (Darnel, 1982, Devoid, 1983, Hack, Goble, Memoli, Stott and Krug, 1983). Invariably the standard database package has to be modified to suit the specific requirements of the clinical engineering department. Such modifications are sometimes done by the clinical engineering department, (Devoid, 1983) but are usually contracted out to a software house (Tackel, 1981) or the hospital Medical Informatics Department (Stiefel, 1981). The systems are written in BASIC (Fannin, Weed and Taylor, 1982, Rice, McCusker and Blasingame, 1983), Fortran (Kresch, Hammarman and Schwartz, 1983). MUMPS (Massachussetts General Hospital Utility Multiprogramming System) is also frequently used (Hack, Goble, Memoli, Stott and Krug, 1983, Maloney and Mead, 1982, Moore and Hancox, 1983, Spector, 1981).

2.4 Data input/output

On-line, interactive systems are generally employed using menu-driven screen displays. One batch-process system is reported (Shaw and Fox, 1983). Small microcomputer systems consist typically of a single screen, keyboard and dot matrix printer (Aichinger and Kempf, 1982, Jones, Bright and Yonovitch, 1983). Larger systems are multi-terminal systems (Darnel, 1982, Katz and Buckley, 1981, Kresch, Hammarman and Schwartz, 1983, Maloney and Mead, 1982, Rice, McCusker and Blasingame, 1983, Tackel, 1981).

Usually technical staff will enter or modify data directly. Security passwords are used extensively (Kresch, Hammarman and Schwartz, 1983, Moore and Hancox, 1983, Stiefel and Welker, 1981). To reduce input and storage requirements standardized codes are frequently used (Ben-Zvi,1983, Harrison, 1982, Health Devices, 1979, Stiefel, 1981). Data is sometimes entered from reports (filled in by the technical staff) by datatypists (Jenkins, 1981) or mark sense readers (Kresch, Hammarman and Schwartz, 1983).

2.5 System applications

The applications common to most of the systems are preventative maintenance scheduling, equipment history record keeping and report generation. Further applications include

* accounting and billing (Fannin, Weed and Taylor, 1982, Harrison, 1982, Maloney and Mead, 1982),
* word processing (Maloney and Mead, 1982, Stiefel, 1981, Tackel, 1981)
* electronic mail (Maloney and Mead, 1982),
* operations research (Furst, Spiegel and Hamilton, 1983),
* statistics (Aichinger and Kempf 1982, Betts and Hamilton, 1982, Katz and Buckley, 1981, Maloney and Mead, 1982),
* spares inventory reorder management (Darnel, 1982, Furst, Spiegel and Hamilton, 1983),
* cost containment (Darnel, 1982, Fannin, Weed and Taylor, 1982, Furst, Spiegel and Hamilton, 1983, Hack, Goble, Memoli, Stott and Krug, 1983),

* analogue data acquisition (Katz and Buckley, 1981, Tackel, 1981)
* automated equipment testing (Katz and Buckley, 1981)

2.6 Advantages and disadvantages

Very few disadvantages are quoted in the literature; there was the disruption caused by the initial installation (Secunda, 1983), the large volume of data that has to be encoded and/or entered initially (Secunda, 1983, Stiefel, 1981) and computer malfunctions (Moore and Hancox, 1983). The general advantages quoted by almost all are less paperwork, more accurate and reliable records and the availability of statistics and reports that simply are not possible with manual systems. Other advantages are: staff reduction (Darnel, 1982, Hack, Goble, Memoli, Stott and Krug, 1983), increased credibility and visibility of clinical engineering department (Darnel, 1982), faster reponse to service requests (Loeb, 1981, Stiefel, 1981), good malpractice insurance rating (O'Donnell and Segal, 1981), meets JCAH requirements (Schipper, 1981), equipment downtime reduction (Hack, Goble, Memoli, Stott and Krug, 1983), facilitates queries (Aichinger and Kempf 1982, Kresch, Hammarman and Schwartz, 1983), cheaper than manual system (Loeb, 1981).

2.7 New trends in computerisation

When clinical engineering was still a new discipline, its needs had a low priority with most hospital managers. Consequently most computer systems were of a small scale.

Since the national recognition of the discipline in the USA and Canada, the scope of the discipline has increased enormously (AAMI, 1985). This has placed new demands on computer systems for clinical engineering. The activities of clinical engineering have been defined systematically (AAMI, 1984) paving the way for a systematic approach to computer systems. At least one such computer system is available commercially (ECRI, 1986).

2.8 Surveys

Several surveys have been conducted in the USA to determine the scope and effectiveness of clinical engineering (Baretich, 1986, Caceres et al 1986, Johnston, 1985, Boxerman and Gribbens, 1986). Indications are that similar studies were conducted in other countries but no references to the results could be found (AAMI, 1984). A report was published describing the results of the West German experience and highlighting the financial viability of clinical engineering. (Schwing, 1987). In a survey by Baretich (Baretich, 1987) the lack of consensus of department names for clinical engineering at different hospitals, is highlighted.

The surveys carried out in this thesis indicate that the most widely read clinical engineering journal in South Africa is the Journal of Clinical Engineering. The publishers conducted a survey to determine the profile of its readers worldwide (Pacela, 1987c). The journal regularly conducts surveys of clinical engineering in the USA (Pacela, 1987b). The surveys conducted in the RSA by the author used similar categories in an attempt to be able to compare RSA results with those of the USA.

2.9 Organisational position

Most surveys indicate that clinical engineering departments are placed organisationally under the hospital engineering department, also called the maintenance department (Pacela, 1985 & 1987). Most clinical engineers cite this as one of their major problem areas (Caceres 1974, Zerkin 1987, Anon 1987).

2.10 New clinical engineering activities

Besides the original activities associated with biomedical equipment, many clinical engineering departments have branched out into new areas. Radiology and laboratory equipment have been added to the list (Baumeister, 1987) and is today standard for most clinical engineering departments.

Many clinical engineering departments are now active in the clinical setting as part of the clinical team. Under these circumstances complex instrumentation is set up, monitored and run (Edelson and Tackel 1987, Moody 1987).

As computers proliferate in hospitals, the repair of data processing equipment (Robinson, 1987) is a cost effective new area for clinical engineering. In the data communications area clinical engineering departments look after networks, terminals, modems and local area networks (Prilides 1987, Tackel and Schwartz 1987).

Because clinical engineering has expertize to deal with technology in a generic sense, almost any general technology can fall within its ambit. This includes photocopiers, business machines, typewriters, telephones (Secunda, 1987a). Other activities quoted include architectural/facility design, strategic planning and even public relations (Ben-Zvi, 1988).

2.11 Clinical engineering performance norms

Since its inception in the sixties, the norms or standards that were applied to clinical engineering concentrated mainly on the services rendered rather than the cost (Caceres, 1980) ie. how many services were rendered and how well? Some excellent standards documents were compiled (by the Joint Commission for the Accreditation of Hospitals, the Association for the Advancement of Medical Instrumentation and the American Society of Hospital Engineering) to guide clinical engineering departments (St Clair and La Brenz 1986, AAMI 1984, ASHE, 1982). These norms were described in prose rather than in parameters that could be measured. There was no real incentive to reduce costs because most medical aid schemes paid a percentage of a treatment after the event irrespective of the cost (Fenningkoh, 1987). Surveys conducted in the early 1980's reflected the norms of activities of clinical departments of this period (see paragraph 8 above).

Since the introduction of prospective payment schemes the emphasis moved to productivity and cost-effectiveness (Furst, 1986). Although these concepts are generally well understood, they were found to be difficult to apply to clinical engineering. Different centres used different definitions of productivity and inter-institution comparisons turned out to be almost impossible (Johnston, 1987). Much debate ensued and numerous productivity, cost-effectiveness and other performance norms have been defined. (Shaffer 1985, Neuhausel 1985, Hashem 1986, Mahacheck 1987, Betts, 1987, Keil and Camplin 1987). Bauld has attempted to compile standard terminology and definitions (Bauld, 1987). In early 1987 Fenningkoh published a productivity manual (Fennigkoh, 1987) that suggested that clinical engineering departments should become profit centres. It introduced, as a consequence, the concept that clinical engineering should charge for its services. Although attractive, the concept has many pitfalls (Stiefel, 1988).

In South Africa no work has been done in this area. Clearly a great need exists.

2.12 Education

Clinical engineering education is available at many US Universities and Colleges (Browneller, 1986, Wear and Van Noy). An internship at a hospital is an essential part of the training (Bronzino, 1985, Caceres et al, 1980, Newhouse et al, 1985). This applies to both technical and engineering staff. Many universities are discontinuing clinical engineering programmes as these lead to few PhD's and hence fewer grants (Newhouse, 1983). Hardly any facilities exist in South Africa (Muller, 1985).

An in-depth survey was conducted among practising clinical engineers to determine, based on their practical experience, what skills their education should include (Caceres et al, 1980). This survey also looked at what hospital management expected from clinical engineers. In addition to technical skills, management, interpersonal communication and industrial engineering were considered priorities.

2.13 Clinical engineering in developing countries

In developing countries health-care technology poses special problems. (Aston et al, 1985, Ostrom, 1986). These include cultural barriers, lack of logistical support, limited infra-structure and difficult access to information about technology. Clinical engineering has an especially important role to play in these countries but training needs to be appropriate and it must be considered as an integral part of the technology strategy (Krishnamurthy, 1984, Raja and Srinivasan, 1985, Ostrom, 1986). Technology transfer and "train-the-trainer" programmes and equipment standardisation are important approaches (Aston et al, 1985).

2.14 Graphical user interface technologies

The user interface is "the part of the program that determines how the user and the computer communicate"; "it should help the user without getting in his way; it should be easy to learn and efficient to use, it should be consistent, logical, natural, amen." (Herbst, 1988 p 2 - 7).

The user interface has consequently been the subject of much study (Mosier and Smith, 1986, Cakir, 1986). The use of graphics can improve the user-interface (Mute and Mayson, 1986, Whitefield, 1986). Employing standards or guidelines to design the user interface will enhance it considerably (Malde, 1986, Smith, 1986, Stahl, 1986).

Research work at Stanford and Xerox led to the commercial use of graphics both to create images on the screen and as the user-interface (Lu, 1986). The Apple Corporation brought that to the personal computer level with products like the Apple Lisa and later the Apple MacIntosh (Lu, 1986). Two subsequent graphics standards have emerged, WINDOWS by Microsoft and GEM by Digital Research (LU, 1986) that are suitable for DOS-based personal computers. The WINDOWS interface has become the dominant standard (Grayson, 1987, Ellison, 1987). Software development in the WINDOWS environment is more difficult so applications are not yet very numerous but growing in numbers (Fastie ,1987). One manufacturer has addressed this problem by producing tools including expert systems to facilitate development (HP, 1987). The WINDOWS interface permits multitasking and makes the multi function work station on a personal computer a reality which leads to improved productivity. (Gebert, 1985, Sumner, 1986).

There is, however, a growing need to connect many workstations together on a departmental network to permit the sharing of resources and data. (Tappscott, 1986, Ginsburg and Rappaport, 1986). Microsoft has announced together with IBM a new operating system, OS/2, that will use the same WINDOWS interface but also facilitate multi-user operations on local area networks (Anderson, 1987, Mirecki, 1987).

CHAPTER THREE METHODS

3.1 Overview of methods

Making decisions is a major function of management. The design and use of decision support tools are well covered in the classical textbooks on management. Taylor and Taylor (1987) provides a lucid review article covering such tools as Monte Carlo simulation, decision trees and linear programming.

The big computer companies such as IBM, Unisys and ICL have produced methodologies to design computer-based decision support systems. One such methodology was used by Groote Schuur Hospital (GSH 1981). The basis of these methodologies is to analyse an existing company or organisation and to describe it as a system consisting of several components. Then the information needs and their respective priorities are determined for the different components of the organisation. Based on the information needs of all the components, an appropriate computer system is designed.

Performing such analyses on an existing organisation is comparatively easy. It has been employed in the clinical engineering field in the U.S.A. by several authors, (Baretich, 1986, Johnston, 1985, Boxerman and Gribbens, 1986) to construct models of clinical engineering (although not with the express purpose of designing a corresponding decision support system).

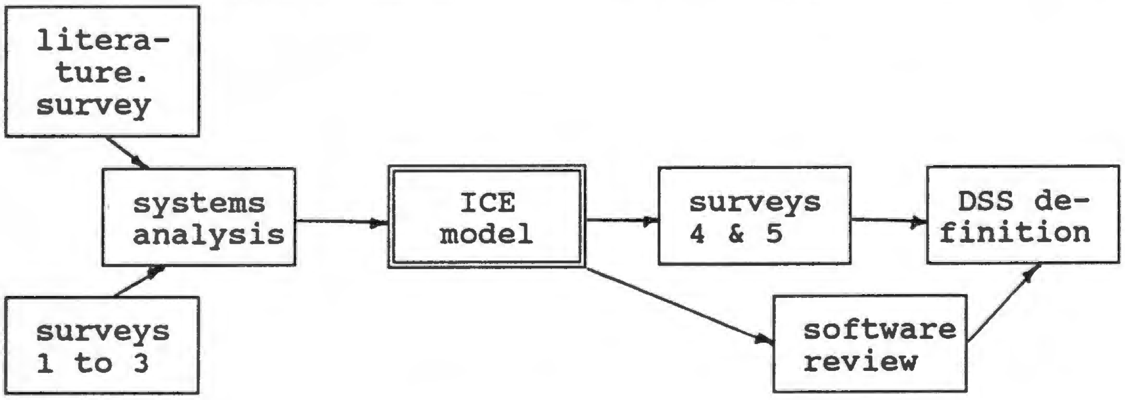

Figure 3 Outline of the thesis method.

Using these methodologies directly in South Africa is not possible because clinical engineering as a discipline is very new in South Africa and exists only in embryo, as it were, at a few hospitals. A new methodology had to be devised that would permit the synthesis of a clinical engineering system (figure 3).

In this thesis project an approach consisting of five main elements, was employed:

1) An exhaustive literature survey was conducted and a bibliography compiled.

2) A large number of surveys and interviews were conducted to analyse:

(a) the existing health-care technology environment of South Africa in which clinical engineering is to function as well as

(b) the acceptability of the proposed idealised clinical engineering model.

3) A systems design methodology, adapted from the systems engineering discipline, was applied to the synthesis of a clinical engineering system.

4) Existing commercial software packages, that could be used as tools in the decision support system, are reviewed.

5) The definition of an appropriate decision support system.

These five elements of the thesis are discussed in more detail below:

3.2 The literature survey

A major purpose of the literature survey was of course to determine what other researchers have done in the area of systems design in clinical engineering. An additional purpose was to provide input to the systems synthesis methodology whose starting point is an analysis of the functions of the system to be synthesised. As clinical engineering is still an evolving discipline, different clinical engineering centres in the world have developed new, unique functions and have reported these in the literature. In this thesis, these new functions are combined synergistically with the standard, well defined functions of clinical engineering that are described in the text books.

3.3 The survey of the health-care technology environment

Five surveys were conducted : Three national surveys, by mail, to determine the actual health-care technology environment in South Africa and two surveys, by interview, to determine the acceptability of the idealised clinical engineering model. These are listed in Table 1.

SURVEY	TARGET GROUP	TITLE
1	Hospital management and engineering departments	Survey of facilities, staffing, wages for clinical engineering departments in hospitals
2	Medical equipment company management	Survey of facilities, staffing and wages for medical equipment manufacturers/suppliers
3	Clinical engineering personnel of hospitals and companies	Salary survey for individual clinical engineers and technicians
4	Health-care administrators clinicians, nursing	Acceptability of the idealised clinical engineering department model
5	Medical equipment companies	Acceptability of the idealised clinical engineering department model to medical equipment suppliers.

Table 1 A list of surveys

It was recognised that some clinical engineering functions were being performed at hospitals by departments and individuals having varying titles. For the purpose of the surveys, a generalised job description was used that defined the different categories or levels of personnel that could be used (appendix A).

As the questionnaires would only be sent out to a random sample of hospitals, the hospital geographical data was obtained from the South African Hospitals and Nursing Yearbook (Engelhardt 1986).

As a large proportion of hospitals are government-funded, their environment is influenced by a host of policies and regulations. For this information the appropriate government bodies were consulted.

SURVEY 1 (250 Questionnaires were mailed out - see Appendix B)

Survey 1 consists of two parts: Part A determines basic hospital specific data and Part B clinical engineering specific data. This allows a correlation to be made between the clinical engineering data and the size, type and geographical location of the hospital.

Of particular importance in Part B are questions 4 and 9 which look at the amount of technology involved. Question 10 addresses the availability of computer facilities; a question that has bearing on an eventual computer-based decision support system.

SURVEY 2 (150 Questionnaires were mailed out - see Appendix C)

Survey 2 is largely similar to Survey 1 except that Part A addresses medical equipment company data. This enables a correlation to be made between the clinical engineering data and such company parameters as range of equipment represented, size of company and local manufacture interests.

SURVEY 3 (250 Questionnaires were mailed out - see Appendix D)

In this survey the actual current status of clinical engineering personnel was assessed. In question 9 their computer literacy as well as access to computer facilities is gauged with the eventual computer-based decision support system in mind. Other parameters surveyed include qualifications, experience and salaries.

SURVEY 4 AND 5 (50 Interviews were conducted - see Appendix F & G)

The goal of these two surveys was to determine the acceptability of the idealised clinical engineering (ICE) model to hospital and medical companies respectively. As the ICE model is totally new (it is the result of this research) and hence unknown in South Africa, a survey by interview was used. The interviewees were presented with a short, standard presentation of the ICE model (appendix E). After the presentation, the interviewees were requested to complete a questionnaire and return it by mail. An attempt was made to obtain a large cross section of questionnaire and return it by mail. An attempt was made to obtain a large cross section of experienced people from government, private, and teaching hospitals as well as health-care administrators and planners. Experience was especially sought in those areas that the ICE model is to address - equipment acquisition, user training, incidents and court cases.

The questionnaires allow for general comments. Notes were also made of the questions and discussions that followed the ICE model presentation.

In question 4 an attempt is made to gauge the interviewees' comprehension of the concepts of the

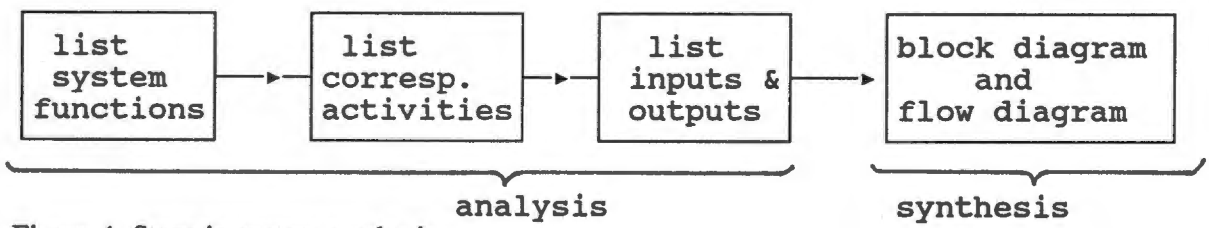

Figure 4 Steps in system synthesis

ICE model as that could have an influence on how accurately the questionnaire is completed.

3.4 The systems synthesis methodology

The ICE model is a complex multi-disciplinary system. As a consequence the methodology used to synthesise the ICE model is also complex. Therefore it is described only briefly here for clarity. A more rigorous description is given in Appendices I and J. The methodology consists of an analysis portion and a synthesis portion (see figure 4).

According to the general systems theory, a system can be described as follows (figure 5):

The system is described by

(a) the set of inputs and outputs

(b) the relationship between outputs and inputs

(c) the activities of the system

(d) the elements that the system consists of, how they are interconnected and how their status

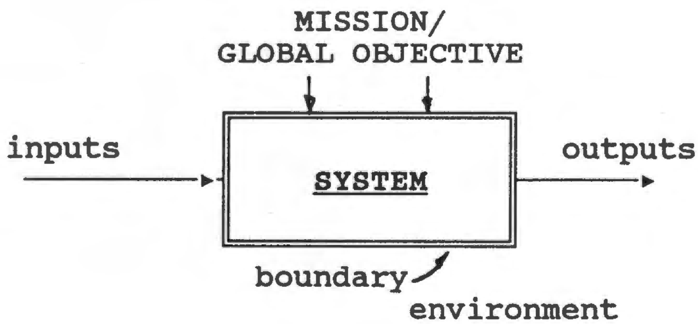

Figure 5 A general system

changes with time.

The objective of a system is associated with the desired results to be obtained by the system during the execution of its functions. A statement of the objective should include:

- the results to be obtained (output)
- the global activity that produces the desired results
- a quality or standard associated with the desired results.

In this context then, the objective of the clinical engineering system is to provide and support (global activity) technology (output) in a cost effective and safe manner (standard). Figure 6 shows the clinical engineering system in relation to the hospital.

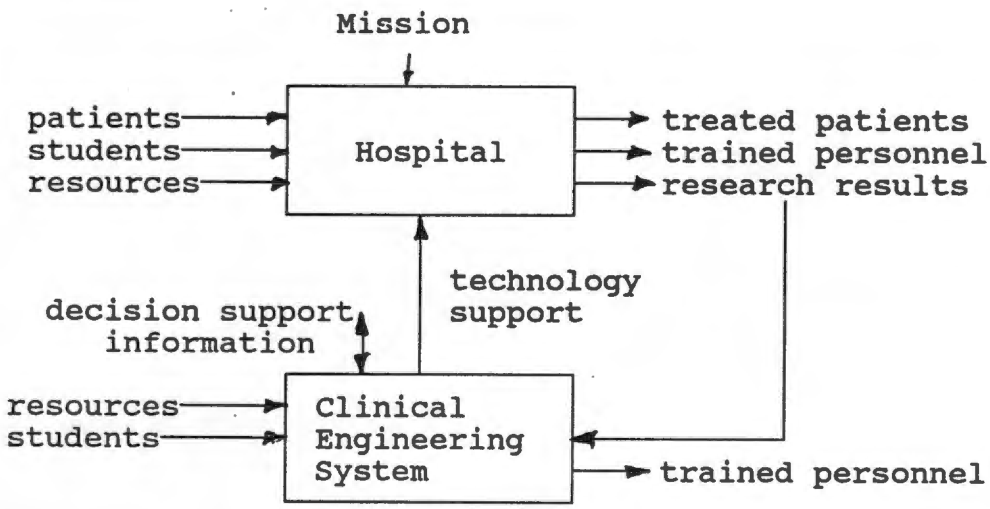

Figure 6 The clinical engineering system in the hospital environment

The synthesis of the ICE system was done in two basic phases

(1) Formalisation of the requirements

(2) System synthesis.

(The details of the actual synthesis process followed, are described in appendix J).

Phase 1: Formalisation of Requirements:

(1) Formulate the objective of the system.

(2) Analyse the environment of the system.

(3) Identify system functions.

(4) Analyse each function and

* specify performance requirements

* enumerate activities that are necessary within the system in order for the function to be realized

* list inputs and outputs for the function with their specifications (range, resolution etc.).

Phase 2: System synthesis

(1) Design the organigram of the system by mapping the functions/activities onto elements and interconnect them.

(2) Design the flow diagram (state-transition structure) of the system so that the required behaviour may be realized.

3.5 Review of commercial software

Due to the effects of sanctions, certain software packages are not so readily available in South Africa. None of the companies that produce software specifically for clinical engineering are presently represented in South Africa. However, companies that advertise clinical engineering software in the various journals were written to for more detailed information.

Brochures and technical specifications were collected on software packages that could be used in the RSA within the various constraints that were determined by this research.

To minimize software development, different commercially available software packages are compared to the information needs of the ICE systems/activities to determine the degree of match. Once the appropriate software is determined, corresponding hardware is selected that would permit the software to run on and satisfy other organisational constraints.

3.6 Development of the decision support system (DSS)

The DSS is developed considering the information needs of clinical engineering on the one hand and the environmental constraints as determined by the research of this thesis on the other.

The DSS, as developed in this thesis, consists of human and organisational components. It also makes extensive use of computer-based tools. The DSS may require a fair amount of software integration and additional development. Approval of the health-care authorities will be required to implement the DSS at a hospital. Software purchases in the public sector are subject to approval by the Commission for Administration.

Therefore the DSS is presented in this thesis only in concept form. The actual implementation of the DSS falls outside the scope of this thesis.

CHAPTER FOUR THE HEALTH-CARE ENVIRONMENT

4.1 General comments

The response to the questionnaires was better than expected (>30%). However for Survey Two (to the medical equipment suppliers) the response was very poor (7 out of the 150). Further investigation revealed that the suppliers were not in favour of this kind of survey and had via their Association decided not to reply to the surveys. Even though confidentiality was guaranteed, they felt that their commercial interests would be compromised. This probably is an indication of the competitiveness of the South African medical device industry. The interaction between clinical engineering departments and the medical equipment suppliers is very important. Fortunately the information requested in this survey is not critical at this stage for the development of the ICE model but could be pursued at a later stage.

Questions dealing with equipment inventory levels, maintenance budgets, etc were not completed in any of the questionnaire returns from the hospitals as records are either not kept at all or are hidden in the hospitals' general records. As a general rule one could conclude that clinical engineering productivity is not monitored at all!

4.2 Survey one (Hospitals & clinical engineering departments - Appendix B)

Questions 3 and 4 (type of hospital and type of care) indicate that a fairly representative sample of the hospital type and size was obtained. The sample of 58 out of almost 1000 hospitals is too small for statistical accuracy. However the results do provide indicators of general conditions and trends.

The awareness of clinical engineering as a discipline (question A 5 `Were you aware of the discipline of clinical engineering before this survey?`) was better than expected but there is scope for promotion of the discipline.

In no return was "clinical engineering" or a derivative given as the departmental title (question B 2 "Department name ?"). In the majority of cases it is the "maintenance department" or simply "the workshop".

Although 48% indicated that they do have an in-house department, repairs were done on a minimal scale. They still made use of the suppliers' services as well. Several hospitals indicated that they shared services with other hospitals (question B 2). This is significant and will be discussed further under geographical data in paragraph 5.4.

Question 4("Equipment serviced by clinical engineering department?") shows a fairly even distribution of areas serviced with a bias toward operating theatre and anaesthetics equipment.

From the returns on question B 7 (personnel), it appears that no engineers are employed. Telephonic enquiries to hospitals known or suspected of employing engineers revealed that there are probably five engineers employed at hospitals countrywide. The average is 5 technicians and about 3 artisans per hospital. See survey three for more details on this subject.

A number of points in question B 11 (Department responsibilities) give cause for concern:

- Firstly, there is a low involvement in preventative maintenance and incoming inspections - both activities that affect equipment safety.
- Secondly, training opportunities are clearly very limited.
- Thirdly, clinical engineering departments are handicapped because of restricted budgets.

4.3 Survey Two (Equipment suppliers - Appendix C)

The response to this survey was quite low(4,7%). Many suppliers indicated telephonically to the author that they would not reply to the questionnaire because it would hurt their commercial interests and that the promise of confidentiality of the results was not enough.

In question A5 ("distribution of companies") it is apparent that Johannesburg, Cape Town and Durban were the main centres for medical device suppliers. In most cases no service centre was available in the other cities.

Question A7 ("origin of imported equipment") shows that a large proportion of equipment is imported from Europe and the USA. This is important from the view of future medical device regulation and hazard notification systems in South Africa.

Question 8 deals with availability of personnel. The private sector also has difficulty in finding personnel (8 (a)). Although they provide in-service training, they do not generally provide basic education.

The number of blank returns in question 9 ("Relationship to hospitals") indicates that probably this was considered to be a leading question. The suppliers would allow hospital staff to do minor repairs but would prefer a service agreement with an inclination towards the comprehensive type rather than a "we will call you when we need you" basis (9 (b) and (c)). This issue was raised more intensively during Survey 5 and is discussed more fully there.

The answers under Part B are too sketchy to draw too many conclusions from. The salary ranges (B7 "salary ranges") are higher than those of the Public Sector, confirming why suppliers indicate that they do not lose staff to hospitals (A9 (e)). Question B9 ("list computer equipment available for use by or dedicated to this department") indicates that technical staff are perceived by their employers to have virtually no access to (or need for?) computer facilities. Survey Three shows a slightly better position when both hospital and supplier technical staff are considered together.

4.4 Survey Three (Clinical engineering personnel - Appendix D)

A number of significant conclusions can be drawn from this survey.

Question 4 indicates that the average age is 42 years while question 6 (a)("qualifications") indicates a large proportion with a relatively low technical qualification - N3, tradesman or only normal school. Yet there is a fair percentage with T3 and higher. The explanation lies in the fact that T3 is still a relatively new technical qualification. Those personnel with the longer experience (Question 5) started working before technical education at Technicons was available, while those with the T3 qualification are younger and with fewer years experience.

Questions 6 (b)("registration") and (c)("membership of societies") point to a high degree of professionalism. Professional registration for technicians by the South African Council for Engineering Technician Registration is still very new and yet a high proportion of respondees have registered. The South African Association for Clinical Engineering is well supported although not universally so.

In question 8("job responsibilities") the emphasis, as expected, is on repairs and supervision. Very little time is devoted to other activities such as training, research and preventative maintenance (see figure 7). The literature indicates that preventative maintenance time should be between 100 and 200 % of time spent on repairs (Hashem, 1986, ECRI, 1984, Caceres, 1980).

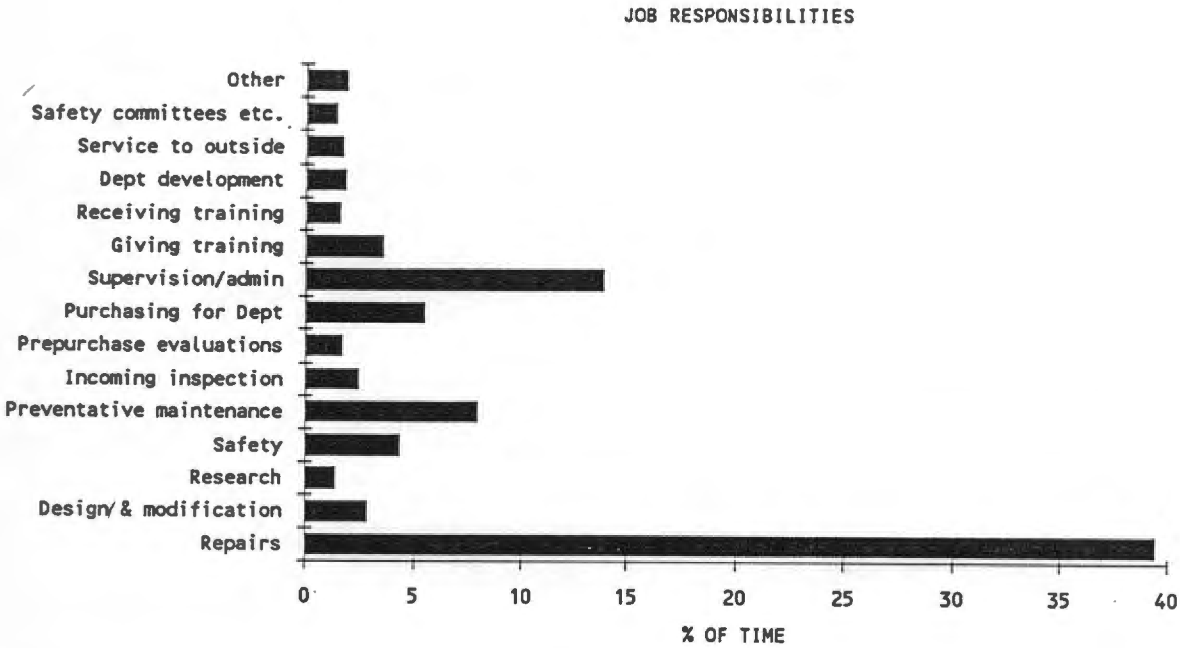

Figure 7 Current allocation of time to various clinical engineering tasks

Question 9 ("computers")shows that a fair proportion of respondees have access to computers, especially PC's. The most frequently used software would be word processing and spreadsheets. The majority, though, do not have access to computers and are not familiar with the basic productivity tools that are available on PC's.

Question 10("which journals do you read regularly") shows that journals are not very widely read - probably age and level of technical training playing a role here. Discipline-related journals such as the Journal of Clinical Engineering are read more frequently.

According to Question 11("Based on experience, inwhich areas would you have liked more training?") further training was considered necessary by some although a large proportion indicated that their training had been adequate. Instrumentation theory, computer theory, physiology and anatomy were singled out as important.

4.5 Geographical data

This data has been extracted from the "Hospitals and Nursing Yearbook for Southern Africa 1986". Table 2 and figure 8 give the geographical distribution of hospitals grouped according to the number of beds (which is an important clinical engineering indicator).

In Appendix L a list of postal codes is given where two or more hospitals are located at the same postal code. Such hospitals are theoretically in close proximity and could be potential candidates for shared clinical engineering services. Table 3 gives an overview of the hospital breakdown by region and compares private versus public funded hospitals.

	# of hospitals						
Area/ city	Pta	Jhb	CT	Dbn	Bfn	Rural	Total
# of beds							
0-100	12	15	25	7	3	335	397
- 200	9	14	9	3	1	102	138
- 300	1	9	3	6	1	89	109
- 400	1	0	1	1	0	32	35
- 500	1	4	0	0	0	22	27
-1000	1	3	2	2	1	46	55
> 1000	4	2	4	3	2	15	30
							TOTAL: 791 > 200 beds: 256 < 200 beds: 535

Note: Hospitals not in the municipal area of the five major cities are considered to be rural hospitals in this table.

Table 2 Distribution of hospitals by city

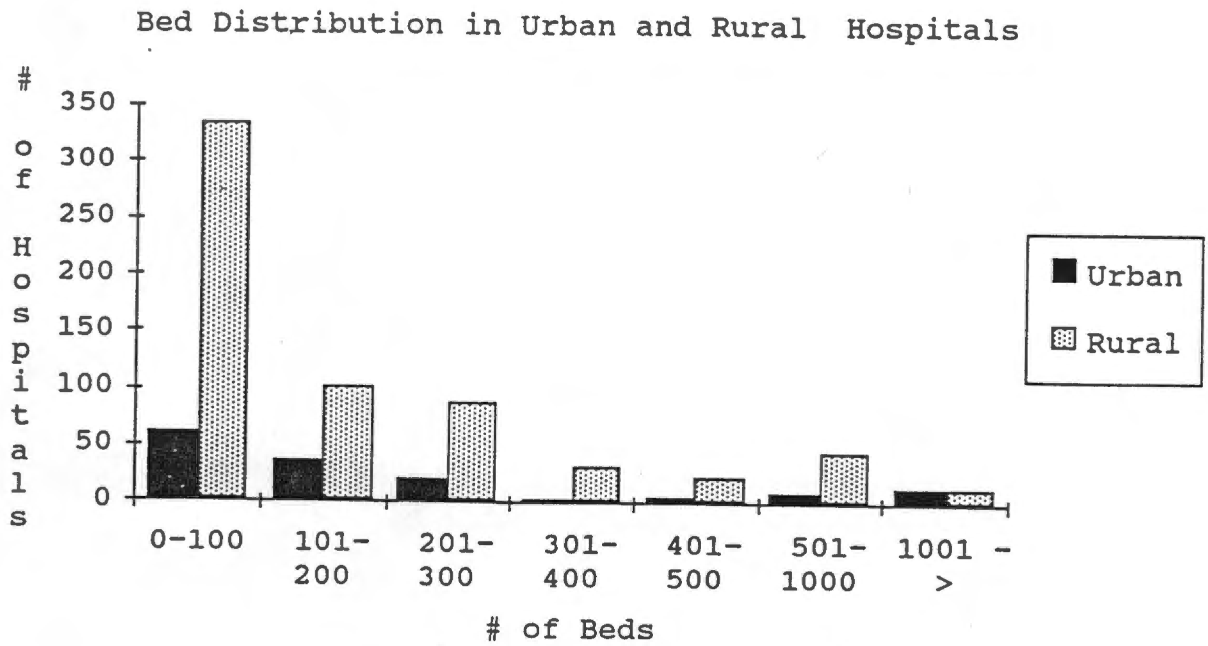

Figure 8 Bed distribution in urban and rural hospitals

RSA (PRIVATE)			
Region	No Hospitals	No Beds	Beds/Hospital
Cape	103	5 661	55
Natal	29	3 656	126
OFS	12	5 696	58
Transvaal	102	10 304	101
Other	95	14 107	461
TOTAL	341	34 321	
RSA (PUBLIC FUNDED)			
Cape	89	17 385	195
Natal	26	11 914	458
OFS	27	5 109	189
Transvaal	69	21 995	319
Other	71	31 778	872
TOTAL	282	88 081	
TOTAL RSA	623	122 402	
TOTAL SWA.	143	8 164	
TOTAL SGS	59	20 911	
TOTAL IS 56	18 270		

legend

SWA: South West Africa
OFS: Orange Free State
SGS: Self Governing States
IS : Independent States

Table 3 Summary of hospital beds (1986 data)

4.6 Geographical Survey

Based on the staffing norms of the ICE model (appendix E) the following staffing estimates can be made of clinical engineering personnel for South Africa(Table 4).It is estimated that there are currently approximately 300 to 600 clinical engineering personnel in South Africa (less than 10 clinical engineers).

No of beds	Technicians	Engineers
100 - 200	138	
200 - 300	218	
300 - 400	175	35
400 - 500	162	27
500 - 1000	500	108
1000+	900	210
TOTAL	2 093	380
ACTUAL	300 - 600	<10

Table 4 Staffing requirements as per ICE norms

Survey Two has shown that the equipment suppliers are located mainly in the three bigger cities. However, from the geographical survey, rural hospitals outnumber urban hospitals 6 : 1. The majority of rural hospitals are below 100 beds and do not qualify for in-house technical staff. So most of these hospitals do not have easy access to technical support.

When hospitals are grouped together by postal code, (see Appendix L) it becomes evident that there are many areas where several smaller hospitals are located at the same postal code and are thus in reasonably close proximity to each other. This makes it possible to provide technical support to these groups of hospitals on a shared-service basis. This concept is already used in several areas (see Survey One).

4.7 Other factors

A number of other factors in the clinical engineering environment in South Africa, that could affect the ICE model, were considered.

(a) Medical device legislation

There currently is no legislation controlling the import or sale of medical devices in South Africa. However the Minister of Health has stated (in his opening address at the SAAAMI seminar on local manufacture at the end of 1987) that the Government was working on this and that an announcement in this regard was imminent.

A large proportion of medical devices is imported from the USA. Legislation in the USA forbids the export of devices, that have not been approved for sale by the Food and Drug Administration, to any country (including South Africa).

The basis of medical device legislation of most countries is the registration of manufacturers and importers. The manufacturers must also subscribe to a system of good manufacturing practice inspection (GMP). For high risk devices additional requirements pertain although these vary from country to country. Reciprocity arrangements exist between many countries whereby they accept each others GMP certificates. South Africa does not actively participate in any of these programmes.

(b) Medical device safety

There is no organised national system for:

* disseminating medical device safety information and hazard notices
* of locating and recalling defective devices
* of collecting data on device-related incidents.

A number of overseas agencies make their information available on request (DHSS, FDA, ECRI, DKI) but this is not well known or exploited. It is envisaged that the Directorate of Radiation Control of the Department of National Health and Population Development will be implementing such a system in the near future(announced by the Minister of Health at his opening address of the SAAAMI seminar on local manufacture in October 1987).

(c) Medical device standards

There are very few South African medical device standards. However, South Africa, under the auspices of the South African Bureau of Standards, is a cosignatory to the IEC and ISO who have already published over a 100 medical device standards. This fact is unknown to the majority of hospitals and few clinical engineering departments have copies of or access to any of these standards. Details of these standards are not covered in any of the existing training programmes.

(d) Health-care strategic planning

Health-care planning in South Africa has to be guided by the realities of our limited resources while striving for the achievement of the ideal health status as defined by the World Health Organisation. In this context it has been stated in the national health plan of the Department of National Health that its goal is to assure the optimal utilisation of resources for the health function. There has been a consequent shift in emphasis to primary health-care and a reduction in spending on technology acquisition and replacement. Existing equipment therefore has to be kept in service for much longer which in turn is placing greater demands on clinical engineering personnel. Many health-care administrators hold the erroneous opinion that technology is limited largely to teaching hospitals. As the emphasis is on primary health-care, it is assumed that fewer technical staff will be required and that appropriate technology implies no technology. As a result the creation of clinical engineering positions appears to have a lower priority in long term strategic planning.

Planning by all concerned with health-care also has to take the threat of sanctions into consideration. There is some interest in the local manufacture of medical devices and the Southern African Association for the Advancement of Medical Instrumentation has been formed as a result. Although technology transfer should be particularly important under the present circumstances, clinical engineering personnel are hardly ever given overseas factory training even when this is available.

(e) Education and training

Until recently no formal clinical engineering education was available in South Africa. Presently the Pretoria Technicon offers a National Diploma in Clinical Engineering in conjunction with the H.F. Verwoerd Hospital which has provided a centre for practical training. SAACE is negotiating with the Cape Technicon for a similar course in the Cape. For engineers the University of Cape Town offers a post graduate diploma in clinical engineering and is planning a clinical engineering speciality option for its B.Sc degree in Electrical Engineering. The lack of suitable employment and career development opportunities has a negative effect on enrollment. Informal training is offered by SAACE to its members in the form of seminars and congresses. If the newly established SAAAMI will follow the model of its American counterpart, AAMI, it will also provide congresses, meetings and a journal.

(f) Engineers in clinical engineering

The surveys show that there are probably less than 5 professional engineers employed in clinical engineering in South Africa. Telephonic interviews with several teaching hospitals (Groote Schuur, Tygerberg, Red Cross, Wentworth, Universitas and HF Verwoerd hospitals) on why this should be indicated that they have great difficulty in being allowed to create clinical engineering posts, even though an engineer post is no more expensive than that of a senior technical post. Another problem appears to be the high demand for engineers in the armaments and related industries. Hospitals that do have vacant positions have as a result, been unable to recruit engineers.

Lack of career development possibilities was mentioned as a problem leading to engineers leaving the health-care field and hampering recruitment. In public sector hospitals, professional registration is a prerequisite for promotion. At present there are no hospitals, with the exception of Groote Schuur hospital, that are properly equipped to provide the training for professional registration.

CHAPTER FIVE THE ICE MODEL

5.1 Description

An overview of the ICE model that was used as the presentation during surveys 4 and 5 is included in appendix E. The actual derivation is described in appendix J.

To make analysis possible, the ICE model is described in several levels of abstraction. These are:

- the general management system
- the ICE system
- the decision support system

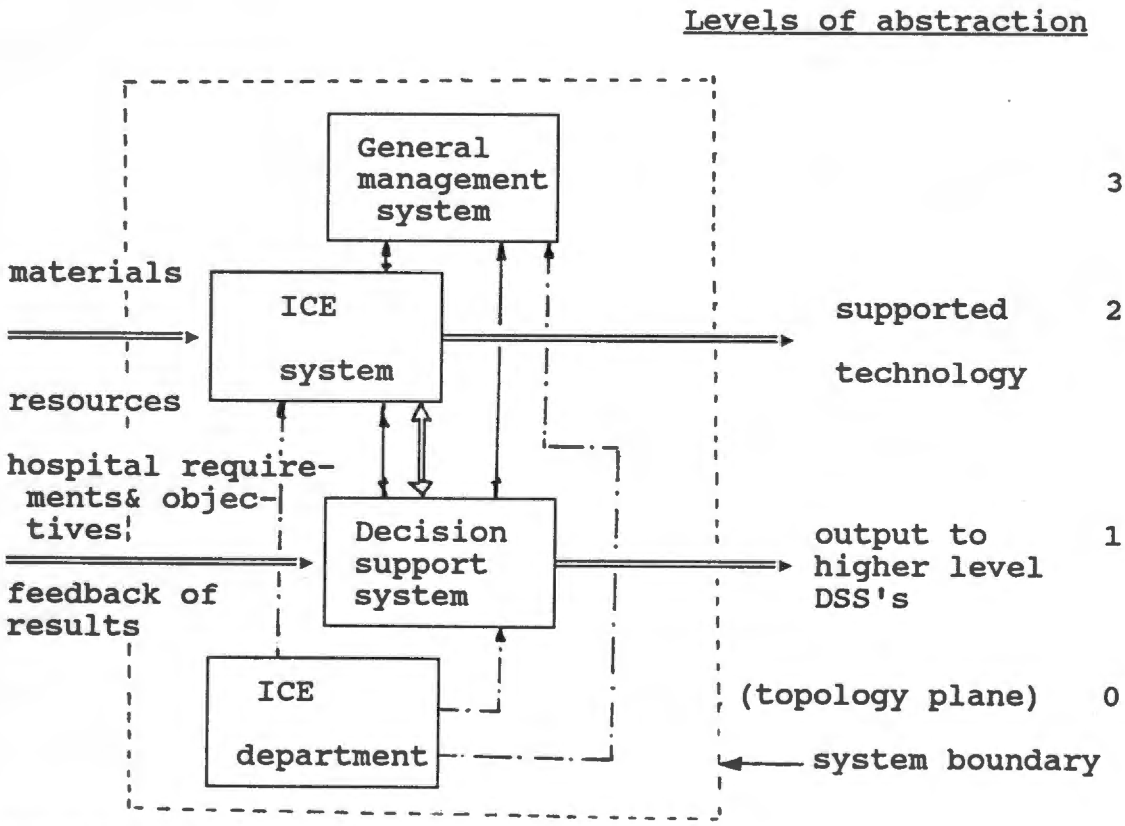

Figure 9 Levels of ICE model abstractions

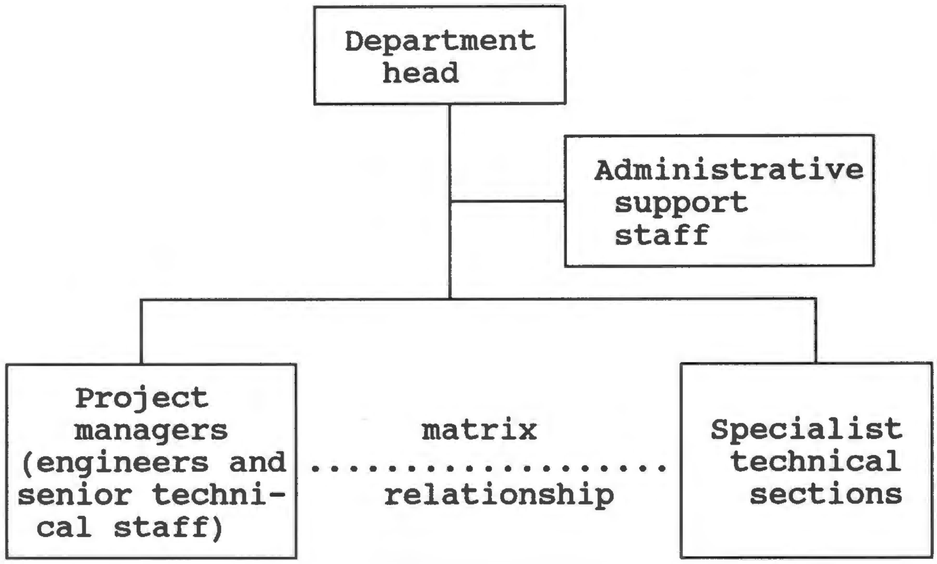

Figure 10 The idealised clinical engineering department (topology plane)

The topology plane, which forms the basis of all other EC-structures is shown diagrammatically in figure 10 and the decision support system hardware in figure 11.

It should be noted that in a large hospital one or several individuals could be allocated to one function whereas in smaller hospitals a single individual could be responsible for several functions. Similarly for small hospitals the technical sections could be a single workshop and some of the ICE functions could even be performed by outside agencies.

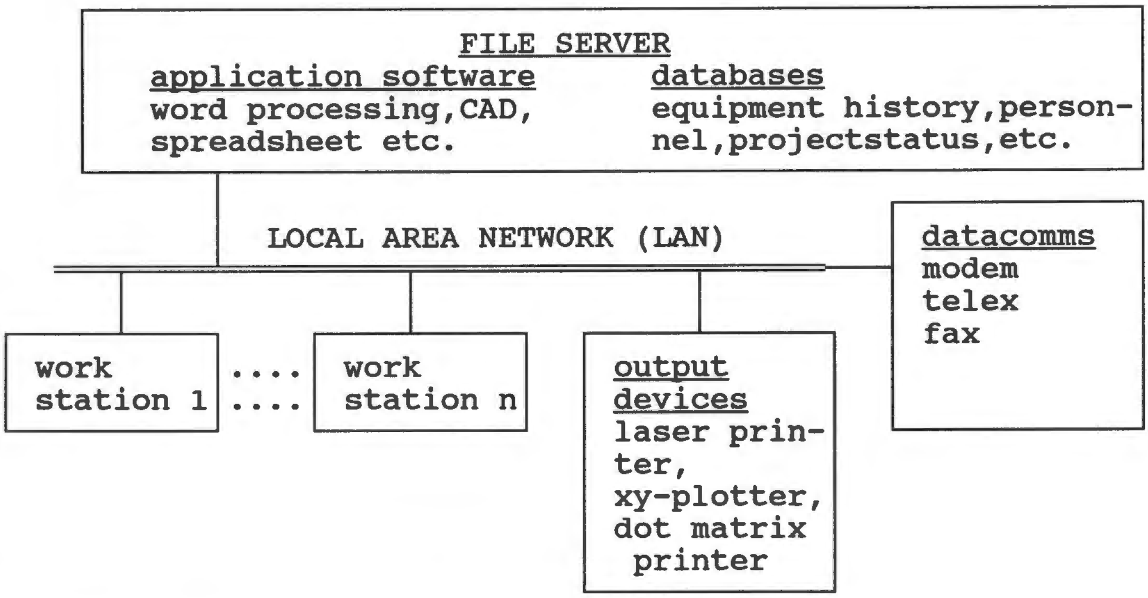

Figure 11 The decision support system hardware

Also for small hospitals the local area network would typically be a single personal computer.

5.2 The ICE model discussion

The support of technology is not as well understood in the health-care world as it is in industry. The ICE model is useful to formally identify the many elements required to support technology that would otherwise go unrecognised by health-care administrators and even by some clinical engineering personnel. It also identifies the organisational links that need be set up.

The staffing norms are based on overseas norms for demographically similar areas but have been moderated by local experience. More work should to be done to ratify these norms.

Many concepts that have been developed in the ICE model are new to clinical engineering in South Africa. This will have training implications and will have to be fed back to the educational institutions.

As one considers decreasing sizes of hospital, the corresponding ICE departments also become smaller. Hence each individual ICE department staff member of a smaller hospital has to perform more of the ICE model functions. He also needs to be familiar with a broader spectrum of technical disciplines. So paradoxically the staff of smaller hospitals generally should be of higher competence and experience.

5.3 Survey Four (Acceptability of ICE to health-care professionals - Appendix F)

Questions A1("current position?") and A3("related experience?") describe the background of the respondees and indicate that the sampled group has appropriate experience and background to be able to give an informed opinion on the ICE model. Few have had experience with court cases - the USA tendency for litigation has fortunately not spread to South Africa.

Question A4("description of ICE model") shows that the presentation was clear and that the basic management topics were familiar. On the other hand operations research and systems engineering were generally new concepts. The overall impression was very favourable although 45% felt that ICE could be too expensive to implement.

The various ICE systems and activities were tested in Question A 5.1("give opinion about ICE systems"). Most systems were considered essential with the expected emphasis on repair and safety activities. Also considered absolutely essential was a call-out or stand-by service. The main exception was research and development which was only considered useful.

In question 5.2 ("opinion about ICE technical sections") the specialist technical sections were rated. Generally all were considered necessary; general electronics, anaesthetics and sterilisation sections were cosidered essential. The newer technology sections (optics, office equipment, data communications etc.) were considered useful but with less enthusiastic support.

Question 5.3 ("opinion about ICE infrastructure")presented a surprise. The respondees showed significantly less support for text processing than the author had expected (still rated useful though). Yet Survey Three showed that it was by far the most popular tool used by clinical engineering personnel.

Staffing norms are considered in question A 5.4("opinion about staffing norms"). In the presentation it was stressed that the norms presented, were based on data from the state of Oregon (USA), which was demographically similar to the RSA (surface area, population density and level of infrastructure - Judd, 1983). The response indicated that the norms were reasonable but for teaching hospitals the opinions were equally divided between too high and adequate.

The general comments include:

- excellent concept
- good control would be necessary
- posts would be impossible to create in present climate
- where would the personnel come from even if posts were created?

The significance of these comments are that the health-care authorities would have to assist hospitals by allocating funds for the creation of clinical engineering positions. The shortage of qualified engineering personnel must be addressed at a national level - probably by the professional societies concerned as well as those government departments involved in manpower/population development.

5.4 <u>Survey Five (Acceptability of ICE to suppliers - Appendix G)</u>

Questions A1 to A3 ("current position, qualifications and related experience?")describe the respondee profile. Although the qualifications are different to those of the health-care professionals of Survey 4, the experience of the suppliers is similar. Again court cases are rare. They also found the presentation clear (question A4). The overall impression was in favour of the

ICE model although 7 out of 10 judged that it would be too expensive. It was considered that ICE would not be a threat to companies.

The opinion on staffing norms (Question 5) was divided. This is understandable as this group would not have had any hospital experience.

During the interviews many similar comments were made by the various interviewees. These can be summarized as follows:

- the ICE model was fine in theory, but real world hospital technical staff were generally incompetent, narrow minded and even hostile.
- hospital staff did not understand the supplier's world and his needs and difficulties.
- when hospital staff worked on equipment it was detrimental to the supplier's reputation and compromised his legal integrity in the event of an equipment related court case.
- the tender system was clumsy, unfair and often manipulated by hospital staff.
- hospital staff and suppliers could work as a team if the hospital staff were trained to recognise the role of the supplier.

These comments indicate that suppliers and clinical engineering departments misunderstand each other's roles. This problem can be addressed by the professional societies concerned.

CHAPTER SIX THE ICE DECISION SUPPORT SYSTEM

6.1 Decision support system development

From the literature and other surveys and the ICE model synthesis, the various clinical engineering activities have been identified as well as the decision support that the activities require. Most of these activities could, in theory, be supported by manual techniques such as cardex filing for example. However, experience has shown that modern computer-based productivity tools can do the task faster and cheaper (in fact in many cases the manual technique is physically impossible because of the scope of the task). Therefore computer-based tools form an important part of the defined DSS.

6.1.1 Basic constraints/requirements

The results of surveys 1 and 2 show that for the most part clinical engineering departments:

- do not have access to mini or mainframe computers
- are not very computer literate
- do not have equipment inventory control systems at their hospitals
- do not have ready access to safety, recall, tender or other equipment related information.
- do not report equipment statistics or incidents to a central point for collation.
- do not keep track of their productivity.

Any decision support system would as a result have to satisfy the following constraints/requirements.

- Buying computers would be difficult for most CE departments (should preferably be on state contract.) Must be compatible with next generation of software to avoid early replacement.
- Users would be casual, informed users. Thus the user interface must be easy to use and standard over the different packages.

- Graphics capability essential.
- Must be able to grow incrementally. Most hospitals will only be able to afford a phased introduction of the system and the staff will be faced with a learning curve.
- Software must be available in a wide range of applications and must be inexpensive.
- Workstations would have to be multi-function workstations - for example computer aided design, database and word processing.

6.1.2 DSS information needs

The information needs of the ICE systems/activities and the generic software package types are compared in a matrix form in table 5 below. The range of required software is clearly enormous.

A= equipment control (preventative maintainance)
B= text processing
C= spreadsheets

D= database
E= project management
F= decision support (Monte Carlo etc.)
G= accounting

Systems & activities	A	B	C	D	E	F	G
A. **PLANNING**							
Needs analysis	E	U	E	E		E	
Value analysis		U	E	U		E	
Strategic planning		U	E		U	E	
Facility planning		U	U	U	E	U	
Research and development		U	U	E	E		
B. **ACQUISITION**							
Equipment evaluation	U	U	E	U	U		
Specification drafting		E		E	U		
Tender/RFP preparation		E			U		
Tender/RFP adjudication	E	U	E	U	U	E	
C. **COMMISSIONING**							
Incoming inspection				E			
Installation					E		
Project management		U			E		E

LEGEND: U - USEFUL
E - ESSENTIAL

Table 5 (part 1) Software requirements for decision support in the various clinical engineering systems

H= CAD and graphics
I= data communications
J= Basic, fortran, C etc.
K= CAE (computer aided engineering, circuit design etc.)
L= analogue data acquisition
M= ATE (automated testing of equipment)
N= expert systems

Systems & activities	H	I	J	K	L	M	N
A. **PLANNING**							
Needs analysis			U				U
Value analysis			U				U
Strategic planning			U				U
Facility planning	E						U
Research and development	E		E	E	E	U	
B. **ACQUISITION**							
Equipment evaluation		U		U	E	U	E
Specification drafting	U						E
Tender/RFP preparation	U						E
Tender/RFP adjudication				U			E
C. **COMMISSIONING**							
Incoming inspection				U	E	U	
Installation	E						
Project management							

LEGEND: U - USEFUL
E - ESSENTIAL

Table 5 (part 1 continued) Software requirements decision support in various clinical engineering systems.

A= equipment control (preventative maintainance)
B= text processing
C= spreadsheets
D= database
E= project management
F= decision support (Monte Carlo etc.)
G= accounting

Systems & activities	A	B	C	D	E	F	G
D. **SUPPORT**							
Repair/calibration	E			E			E
Preventative maintenance	E			E			E
Contract Administration		E		E			E
Design/ modifications	E	U			U		U
Call-out				U			
Safety & standards compliance	E			E			
Inservice training		E					
E. **REPLACEMENT**							
Life cycle costing	E	U	E	E			E
Disposal	E	E		U			
F. **MANAGEMENT**							
Budgeting	E	U	E	E		E	E
Financial control	E		E	E			E
Personnel	E	U		E			
Planning	U	E	E	E	U	E	U

LEGEND: U - USEFUL
E - ESSENTIAL

Table 5 (part 2) Software requirements for decision support in the various clinical engineering systems

H= CAD and graphics
I= data communications
J= Basic, fortran, C etc.
K= CAE (computer aided engineering, circuit design etc.)
L= analogue data acquisition
M= ATE (automated testing of equipment)
N= expert systems

Systems & activities	H	I	J	K	L	M	N
D. **<u>SUPPORT</u>**							
Repair/calibration		U		E	E	E	E
Preventative maintenance					E	E	U
Contract administration							E
Design/ modifications	E		E	E	E	U	
Call-out		U					
Safety & standards compliance		E			U	U	E
Inservice training	E					U	U
E. **<u>REPLACEMENT</u>**							
Life cycle costing			U				E
Disposal							E
F. **<u>MANAGEMENT</u>**							
Budgeting							U
Financial control							
Personnel							
Planning							U

LEGEND: U - USEFUL
E - ESSENTIAL

Table 5 (part 2 continued) <u>Software requirements for decision support in the various clinical engineering systems</u>

A wide range of different software applications would be necessary. This at a first glance would appear to be extremely expensive. If it all had to be developed it certainly would be! Fortunately many commercial packages are available that would greatly reduce the cost.

At this point no specific packages are recommended as computer technology is developing all the time. The final choice should only be made at the implementation stage, should it be decided to implement the ICE model nationally. Some cost estimates based on currently available packages, however, were made as an illustration (see table 8). Should the ICE model be implemented nationally, standardisation of the software packages should be considered. This will reduce costs even further due to "bulk buying", reduce the resources required to support the software and simplify training. Such decisions are in turn influenced by government software purchasing policies as determined by the Commission for Administration. Microsoft Corporation's software would be a potential candidate as they have the widest range of the required software, all with the same type of user interface. Together with IBM they have the largest influence on the evolving computer standards. They have however been less than friendly to South Africa in the past.

A problem area is the equipment control software that is used to keep track of equipment repair and preventative maintenance history. Although there are numerous packages currently available overseas, they are not represented yet in South Africa and there is consequently no support. These packages have generally been written for the American market and are not very suitable for the South African health-care system. They usually are not adaptable by the end user. There are two possible candidates:

- Firstly, the Altman's BME database which is cheap and modifiable to local conditions because the dBase III source code is available.

- Secondly, the ECRI HECS (Hospital equipment control system) which is free of charge* but is presently more rigid in its design as it is written in PL1. It does not interface easily with other software packages.

* Any hospitals that are subscribers of ECRI get the HECS software free of charge.

6.1.3 Hospital types

The configuration of an ICE would be different for each size, type and location. It would range from:

(a) Small hospital with perhaps one technician only doing mainly minor repairs and liaising with equipment suppliers.

(b) Medium size hospital with a few technicians providing a wide range of services or a shared service supporting several small hospitals.

(c) Large hospital with a large clinical engineering staff responsible for a large inventory of traditional equipment.

(d) A teaching hospital with state of the art equipment and research and development activities to support.

6.1.4 Hardware requirements

When considering all the constraints described in the paragraphs above, the only possible hardware solution is a selection of IBM AT-compatible personal computers and local area networks. This would permit low cost, entry level systems that could grow incrementally and yet provide graphics capability at all levels. Four different workstations would be required:

- workstation (WS 1) for small hospitals
- workstation (WS 2) with more storage capacity for medium size hospitals.
- workstation (WS 3) with minimal storage as a network workstation for large hospitals.
- workstation (WS 4) with high speed and high resolution graphics for scientific and engineering applications at teaching hospitals.

Peripheral devices must be selected to suit. Data communications facilities are required at all levels to permit access to national equipment safety databases. The hardware items and budgetary costs for the different types of workstations are given in table 6 below:

Hardware	WS1	WS2	WS3	WS4	LAN Server
1. AT-compatible +20 MB disk	3500		3500		
2. Fast AT + 40 MB disk		5000		5000	
3. File server +80 MB disk					9000
4. Hercules screen	1000		1000		
5. EGA screen		2500		2500	
6. Tape Streamer		1000			2000
7. Mouse	250	250	250	250	
Plotter		2000		3000	
Dot matrix printer	1000	1000			1000
Laser printer					7000
Line printer					3000
Scanner					3000
Fax card		1000			1000
Modem card	1000	1000			1000
UPS					2000
Total cost per workstation(Rands)	6750	13750	4750	10750	29000

Table 6 DSS hardware requirements(1987 prices)

6.1.5 Software requirements

The typical software packages that would be required on the different workstation types are listed with estimated cost in the table 7. In this case software based mainly on the Windows user interface is used to satisfy the constraints of paragraph 6.1.1. An equipment control programme with such an interface does not as yet exist and will have to be developed.

Hardware	WS1	WS2	WS3	WS4	LAN Server
1. AT-compatible +20 MB disk	3500		3500		
2. Fast AT + 40 MB disk		5000		5000	
3. File server +80 MB disk					9000
4. Hercules screen	1000		1000		
5. EGA screen		2500		2500	
6. Tape Streamer		1000			2000
7. Mouse	250	250	250	250	
Plotter		2000		3000	
Dot matrix printer	1000	1000			1000
Laser printer					7000
Line printer					3000
Scanner					3000
Fax card		1000			1000
Modem card	1000	1000			1000
UPS					2000
Total cost per workstation(Rands)	6750	13750	4750	10750	29000

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Software	WS1	WS2	WS3	WS4	LAN server
Equipment control	4000	4000	500	500	3000
Windows	250	250	250	250	
Works	700				
Word		900	400	400	1500
Excel		900	900	900	
Fox Base		500	200	200	1500
Project		700	400	400	1500
Chart		500		500	
Turbo CAD	250	250			
Auto CAD				4000	
Data cons					500
CAE		400		400	
DSS		400		400	
Accounting		400		400	
Data Acq				5000	
ATE				2000	
Novell					4000
Elect Mail					500
Expert		200	200	200	
Basic		300	300	300	
Total cost per workstation (Rands)	5200	9700	3150	15950	12500

Table 7 Software requirements for the workstations(1987 prices)

6.1.6 Quantities and costs

By looking at the hospital statistics given in table 2 and the costs per workstation of tables 6 and 7, an estimate can be made of the quantities of wokstations required if the ICE model were implemented on a national scale. This is shown in the table 8 below:

Software	WS1	WS2	WS3	WS4	LAN server
Equipment control	4000	4000	500	500	3000
Windows	250	250	250	250	
Works	700				
Word		900	400	400	1500
Excel		900	900	900	
Fox Base		500	200	200	1500
Project		700	400	400	1500
Chart		500		500	
Turbo CAD	250	250			
Auto CAD				4000	
Data cons					500
CAE		400		400	
DSS		400		400	
Accounting		400		400	
Data Acq				5000	
ATE				2000	
Novell					4000
Elect Mail					500
Expert		200	200	200	
Basic		300	300	300	
Total cost per workstation (Rands)	5200	9700	3150	15950	12500

Table 7 Software requirements for the workstations

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workstation type	WS1	WS2	WS3	WS4	LAN server
hospital type					
Small	120				
Medium		60			
Large			240		60
Teaching			60	20	20
Total quantity	120	60	300	20	80
Cost x R1000 (hardware and software)	12	25	8	26	40
Total cost (xR-MILLION)	1,44	1,5	2,4	0,5	3,2

Table 8 National potential quantities and total cost of DSS workstations (1987 prices)

In this table it is assumed that there was a potential of 50 shared service sites (see Table 3) that would together qualify for a WS1 workstation. Further for large and teaching hospitals an average of 4 workstations per local area network was assumed.

6.1.6 Survey of commercial software packages

There are many commercially available software packages that could be used in the decision support system. These are listed in Appendix H.

workstation type	WS1	WS2	WS3	WS4	LAN server
hospital type Small Medium Large Teaching	 120 	 60 	 240 60	 20	 60 20
Total quantity Cost x R1000 (hardware and software)	120 12	60 25	300 8	20 26	80 40
Total cost (xR-MILLION)	1,44	1,5	2,4	0,5	3,2

Table 8 National potential quantities and total cost of DSS workstations

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6.1.6 Survey of commercial software packages

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CHAPTER SEVEN CONCLUSIONS

7.1 Organisational position

The ICE department has to function in the larger health-care system in an integrated fashion. As such it is also one of the major inputs to higher level decision support systems.

For this to be possible, there needs to be a close, more direct link with hospital management. However, traditionally, clinical engineering personnel have been allocated to "the workshop" which is typically stuck away in the basement or outbuildings. To further compromise the interaction with hospital management, personnel of too low level are appointed and then put organisationally under the hospital maintenance staff (see survey 3). Medical superintendents simply do not make a habit of walking through the boiler house, going past the waste disposal drums to the shack outside to discuss strategic planning with a "technician" in dirty overalls!

This was also the situation in the USA in the beginning. Today it is not uncommon to find clinical engineers on the hospital management team in their own right or even in some cases as the hospital chief executive (Pacela,1987b).

Traditional perceptions will not change overnight. Clinical engineering departments must earn and deserve the correct organisational positions. Two important actions by the appropriate authorities (provincial administrations and the Commission for Administration in the case of public hospitals) are urgently required for this to be possible:

* keeping clinical engineering departments separate from plant maintenance departments and
* appointing more engineers in clinical engineering departments.

In this way an environment will be created where the appropriate organisational position for the ICE department can develop over time, on merit, to mutual benefit of all.

7.2 The ICE-equipment supplier relationship

The interviews during the surveys indicated strongly that the relationship between clinical engineering and equipment suppliers is rather strained. The major reason for this was clearly ignorance on both sides of the other party's role, needs and problems. Yet they are interdependent on each other.

Clinical engineering personnel are at the coal face where they get to know the vagaries of the equipment under their care very well. They also attend to the nuisance calls which make up more than 50% of all faults but usually take less time to fix than it would take an agent to even travel to the hospital.

The suppliers generally desire to have service agreements as this would provide "bread and butter" incomes as well as an opportunity to promote sales during service calls. They also fear that their legal liability would be adversely affected when persons not in their employ work on equipment that they distribute.

The result has been accusation in both directions of profiteering, incompetence, red tape, bribery and many more. This is a very unpleasant, counter productive and unnecessary situation.

Experience indicates that both parties are necessary and should co-exist synergistically. This is eloquently described in the AAMI recommended practice for medical instrumentation departments (AAMI 1984).

The suppliers cannot provide the ICE services as cost effectively as the clinical engineering personnel. For example, attending to minor equipment problems or giving a nurse advice on how to operate a piece of equipment typically takes less time than it would take the supplier to travel to the hospital. Many ICE functions such as strategic planning and tender adjudication cannot be provided by the suppliers at all.

On the other hand in many cases, the supplier can set up a special servicing infrastructure because of economy of scale that would not be cost effective for a hospital with only a few devices to support. The supplier is also the link with the manufacturer - an aspect which is becoming increasingly important as equipment becomes more sophisticated. In some cases only the factory has the necessary skill and infrastructure for repairs.

The solution lies in education. Appreciation of the roles of respective parties should be taught as part of the basic clinical engineering education. The respective professional societies (SAACE and SAMED), as well as SAAAMI, could play an important role in this regard.

7.3 Feasibility of the ICE model

When the feasibility of implementing the ICE model in South Africa was discussed with the interviewees during surveys 4 and 5, an intriguing observation was made. Most of the interviewees felt that the ICE model was satisfactory, implementable and acceptable but at the same time that it would be considered too expensive to implement by the health-care authorities.

One problem was that most of the interviewees did not have direct control over which posts they were allowed to create and fill. They could not employ any savings made on equipment purchases and repairs to pay for additional personnel. A more important problem is that for the most part nobody knew exactly how much was spent on equipment and what proportion could be saved. Nor could they quantify the monetary value of the risk if they did not have the ICE department. The bottom-line is that clinical engineering does reduce overall technology costs.

The quantities of personnel and corresponding decision support systems mentioned in paragraph 6.1 above may seem enormous, but when considered in the context of the total health-care complement of South Africa, it is very realistic. For example the average number of clinical engineering personnel per hospital or per bed is still orders of magnitude less than the corresponding number of nurses or doctors.

Although accurate statistics could not be obtained for all the parameters, a reasonable estimate of the cost implications of implementing the ICE model on a national scale can be derived as follows:

Value of installed medical equipment

The total value of medical equipment in South Africa can be calculated by taking the average number of beds multiplied by the average number of devices per bed as per the ICE norms(see Appendix E):

	hospital size		
	small	medium	large
# of hospitals ave beds/hosp.	250 200	140 400	110 700
# of beds	50000	64000	77000
devices/bed cost/device (average)	4 1000	7 2000	11 5000
Cost (x R-Million)	200	900	000
TOTAL VALUE OF EQUIPMENT: R 5 100 000 000			

Table 9 Estimated value of installed medical equipment

Potential savings

Note: the values calculated below are not based on actual statistics but are taken by way of example to ilustrate the order of magnitude of savings that can be achieved.

The average service costs range from 5% to 10% p.a. of the purchase value (industry rule of thumb):

= 250 to 510 R-million p.a.

A 10% reduction in these service costs due to ICE would thus amount to a saving of:

= 25 to 51 R-million p.a.

Assuming arbitrarily, a 0,1% improvement in nursing and clinician efficiency due to improved equipment working condition, lower failure rate and shorter downtime, a national saving on their salary (assumed to be of the order of 1000 R-million p.a. for this calculation) would amount to:

= 10 R-million p.a.

If the average lifespan of the equipment of 5 to 6 years can be extended by 5 to 10% due to good maintenance by ICE, the annual saving on equipment replacement costs would amount to:

= 8 to 16 R-million p.a.

This represents a typical potential annual saving because of ICE of:

Annual saving due to ICE = 38 to 76 R-million

Cost of ICE

Taking the ICE staffing quantities of table 4 of approximately 2400 at an average salary of R 30 000 (see Survey 3), gives an annual ICE salary bill of :

= 72 R-million p.a.

Allowance of 60 % must be made for overheads including rental of floorspace and test equipment:

= 42 R-million p.a.

The cost of the DSS (table 8) is approximately 10R-million which amounts to an effective annual cost, for a typical 6 year lifespan of computer equipment, of 1,6 R-million + 1 R-million for maintenance (10% of the purchase price) giving a total of :

= 2,6 R-million p.a.

This brings the total annual costs of the ICE model and its decision support system, if it were implemented on a national scale, to:

Total cost of ICE and DSS = 116.6 R-million p.a.

From these estimates alone it can be seen that the cost of ICE would be of the same order than the savings that it would bring about. So it would cost the South African health-care system very little extra to what it is already spending on technology to introduce the ICE model. There could even be a reduction in cost. On the other hand it would gain valuable additional services such as preventative maintenance, safety inspections and many more. Eventually it is the patient that gains in that his expenses and risk of injury will be reduced and the health-care Rand will go further.

There is a major obstacle though, and that is the enormous shortage of qualified personnel. Even if one wanted to implement the ICE model today, it would not be possible. At the present capacity of the educational institutions it would take more than a decade to train the required personnel! Only a gradually phased implementation can be feasible. If it is developed in a structured rather than a haphazard manner, the growth pains and associated implementation expenses will be minimized.

7.4 Recommendations

The surveys indicate that public hospitals would have difficulty in initiating the implementation of the ICE model as they have little control over the allocation of funds or the creation of posts. It can also not be expected of private hospitals to initiate something that is of national scale and interest. The implementation should therefore have to be introduced and managed by the government (the Department of National Health in cooperation with the Provincial Administrations).

7.4.1 The ICE model and in particular the staffing norms should be formally adopted. Hospitals should then be encouraged and assisted to progress to the staffing levels of the norms over a reasonable period of time - 5 to 10 years.

7.4.2 More engineers must be appointed in the public sector hospitals. To make this practical, an intensive recruitment programme must be launched. Funding must be made available to provide the first group with an internship training at a teaching hospital such as Groote Schuur before they are placed in their final positions.

7.4.3 The level and availability of clinical engineering training must be increased. Curricula should be monitored by the Department of National Health and Population Development and the Department of National Education and the clinical engineering society, SAACE. The certification programme of the SA Board of Examiners for Clinical Engineering should be adopted officially.

7.4.4 The surveys indicate that a large proportion of clinical engineering personnel qualified long before the present day standards existed. A refresher programme should be run for existing senior clinical engineering personnel. This programme could be in the form of regular summer schools lasting approximately two weeks. This "train the trainer" programme will bring senior personnel up to date on standards and practices and will ensure that all speak the same language nationally. They could then go back to their institutions and pass the information on to the rest of their staff.

7.4.5 A phased implementation of the personal computer based system (DSS) is recommended. This is a prerequisite for recommendations 7.4.6 to 7.4.8 to be effective. Funding should be allocated to the provincial authorities for this. Even though the provision of the DSS hardware and software will be contracted out, the project must be coordinated centrally, preferably by the same institution that will implement the national medical device registration and recall system. Private hospitals should also be encouraged to participate.

7.4.6 A national system for medical device registration and the dissemination of safety or recall information must be implemented. This also implies that a standard nomenclature system for medical devices be adopted. The ECRI universal nomenclature system is recommended as this would permit access to information internationally.

7.4.7 In addition to staffing norms, national performance data must be collected so that individual hospitals can compare their performance intelligently. This implies that national performance parameter definitions must be adopted.

7.4.8 A national hot line or electronic bulletin board service must be provided so that outlying hospitals could have rapid access to information on safety and standards.

7.4.9 The surveys indicate that many of the hospitals that would benefit from the ICE model are in the black ethnic regions. Nursing has become a prestige position for black women. Cultural barriers have so far prevented men from entering the technical field but a promotion programme could be the needed catalyst. Promotion of clinical engineering as a career should be part of the population development programme so that this untapped resource could be utilized. Hospitals would then be able to appoint people from the local community.

7.4.10 As can be seen from the geographical survey (4.2.6), many rural hospitals could benefit from shared clinical engineering services. However the hospital that would provide the service should be given assistance to get the project off the ground. In many areas there is a mixture of public and private hospitals. A system of paying for shared services would have to be devised.

7.4.11 The establishment of a single branch or institute of "technology in health-care", probably within the Department of National Health, should be considered where all aspects of technology could be dealt with in a coordinated manner. The aspects would include funding, planning, education, local development, research, appropriateness and impact of technology. Such a body would be well placed to implement the recommendations given above. Not only will clinical engineering benefit enormously, but so will the other disciplines involved in technology such as medical informatics, medical physics, clinical technology and medical graphics.

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APPENDIX A

GENERALISED JOB DESCRIPTION

A1. ARTISAN / MECHANICIAN

Has good manual skills but limited technical education.

General:

Performs skilled manual work and technical work of routine difficulty under supervision. Fills out report forms.

Direction Received:

Works under supervision. Received specific and detailed instructions. Technical work is checked during progress and is reviewed for accuracy upon completion.

Supervisory Responsibilities:

Usually none.

A2. TECHNICIAN

General:

Under general supervision, performs skilled work of average difficulty. Has several years of related education or equivalent experience. Good knowledge of schematics. Maintains records and makes reports.

Direction Received:

Works independently in repair and preventative maintenance programs. Receives general supervision. Selects and requisitions needed parts: coordinates repairs with outside firms.

Supervisory Responsibilities:

May be assisted by artisans or other technicians.

A3. SENIOR TECHNICIAN / TECHNICIAN SUPERVISOR

General:

Works under minimal supervision. Has a significant amount of education or training or equivalent. Performs highly skilled work of considerable difficulty. May coordinate, schedule, or assign work for others. May specialize in certain types of equipment requiring special training or experience. Has comprehensive knowledge of practices, procedures, types of equipment. Skilled with test equipment, schematics, service manuals.

Direction Received:

Works independently in repair, preventative maintenance, incoming inspection, selection of new clinical equipment. Receives general supervision.

Supervisory Responsibilities:

May direct, schedule, or assign work to other technicians and artisans, or may work independently, but is not the overall department or group head.

A5. ENGINEER

General:

Works under minimal supervision. Has degree or substantial equivalent experience. Performs engineering level work of considerable difficulty. Has capability to design and modify medical devices and to do analysis of devices and systems.

Direction Received:

Works independently in design, modification, analysis, equipment selection, evaluation, planning, performance testing or R & D.

Supervisory Responsibilities:

May supervise artisans, technicians, support personnel or other engineers, but is not the overall department head.

A6. DEPARTMENT HEAD

General:

The responsible individual that supervises the clinical engineering department (or equivalent) in a hospital or equipment company. Is usually a degreed engineer or has considerable equivalent management experience.

Direction Received:

Receives direction from the hospital or company management or from an overall head of the division in which the department operates.

Supervisory Responsibilities:

Supervises artisans, technicians, engineers and support personnel.

A7. SUPPORT PERSONNEL

Support personnel such as secretaries, clerks, storekeepers, labourers are not within the scope of this survey.

APPENDIX B

B1. SURVEY ONE

SURVEY OF FACILITIES, STAFFING & WAGES FOR CLINICAL ENGINEE DEPARTMENTS IN HOSPITALS IN SOUTHERN AFRICA

The individual hospital and personnel data obtained in this survey will be kept strictly confidential. Please complete only one copy of this form for a single clinical engineering department. All information should be as of February 28, 1978. Please also have each department employee complete a single copy of the accompanying INDIVIDUAL SALARY SURVEY form and return these either with this form or separately by June 30th, 1987 to: Survey Department, SAACE, P.O. Box 80, Tygerberg, 7505.

A. HOSPITAL DATA

1. Name of Hospital(optional)........................
2. Street Address (optional)........................
   City/Town................ Province/Country ......
   Postal Code ....

3. Type of Hospital (PLEASE MARK APPROPRIATE SPACE WITH A TICK)
   Private, non-profit ..... Private, for profit .....
   Government .... Other ....

4 Type of Care/Size/Occupancy

Short-term stay .... Long term stay ....

general .... Special care (type) ......

University based primary teaching hospital ....

Other teaching hospital ....

Non-teaching hospital ....

No of beds .... Average % occupancy ....

5. Were you aware of the discipline of clinical engineering before this survey?

Yes .....

No .....

How is your equipment repaired/maintained?

technical staff of another hospital ...

equipment vendors ...

Other ...

B. <u>DATA ON CLINICAL ENGINEERING DEPARTMENT (OR EQUIVALENT)</u>

1. Is the clinical engineering department (or equivalent) a separate hospital department?

Yes ...... No ....

If yes, what other department or Individual does it report to?

....

If no, what other department of function is it part of?

....

2. Department name ....

in house dept. .... Multi-hospital shared service ....

independent service vendor ..... Other..............

3. *Name of Dept. head ....*Phone ....

Title ....

*Optional for possible follow up contact.

4. Equipment serviced by clinical engineering department (This may or may not include all of the hospital's equipment).

	Current Year	Last Year
Total No of Devices serviced	....	....
Total Acquisition Value	R...........	R..........

Areas in which your department services.

___ Operating Theatre	___ Clinical Labs
___ Recovery Room	___ Respiratory
___ CCU	___ ECG Service
___ ICU	___ EEC Service
___ Anaesthetics	___ Ultrasound/vascular
___ Radiology	___ Obstetrics/ Gynaecology
___ Radiation Therapy	___ Paediatric/Nursery
___ Occupational Therapy	___ Burns Unit
___ Physiotherapy	___ Dental
___ Haemodialysis	___ Emergency/Trauma
___ General Medical	___ PABX/Communications

Centre

___ Office Automation ___ H.I.S./Computer

___ Medical Graphics/Photography

5. Floor space

	Actual	Planned
Active floor space	....	....
+ Passive Storage Space	....	....
= Total departmental floor space	....	....

6. Department test equipment

Please include all electric test equipment, computers, safety testers, mechanical equipment, tools and other instrumentation owned by this department)

	Actual	Planned
Total dept. equipment	R......	R........

7. Personnel: (Please use the job description given at the end of this survey)

	Actual	Planned
No of Artisans	......	....
+No of Technicians	......	....
+No of Engineers	......	....
+ Support personnel	......	....
Total personnel	.....	....
Vacant positions	......	....
(not included in above)		

8. Salary ranges (before deductions)

	Min. R/annum	Max R/Annum
Artisans	....	....
Technicians	....	....
Sen. Tech	....	....
Technician supervisor	....	....
Engineer	....	....
Department Head	....	....

9. Annual budget for clinical engineering department (or equivalent)

	1986	1987(planned)
Salaries	....	....
+ Repair material/ spare parts	....	....
+ Supplies	....	....
+ Outside services	....	....
+ Capital & test equip.	....	....
+ Other	....	....

10. Computer equipment

(List only computer equipment available for use by or dedicated to this department)

Mini computer (type)............Quantity...........

Micro computer (type)...........Quantity...........

Does the department have substantial access to the hospital's Mainframe computer Yes ____ No ____

Is software operational for: Yes ____ No ____

Preventative maintenance scheduling Yes ____ No ____

Service history database Yes ____ No ____

Labour & timekeeping/billing Yes ____ No ____

Spares inventory Yes ____ No ____

Accounting Yes ____ No ____

Management reporting Yes ____ No ____

Access to databases Yes ____ No ____

(via data comms)

CAD (computer aided drafting) Yes ____ No ____

11. Department responsibilities:

Is your Dept. involved in overall hospital quality assurance? Yes ____ No ____

Do you provide an equipment hazard notification service? Yes ____ No ____

Do you perform regular performance assessment of your own department? Yes ____ No ____

Do you have written test equipment calibrated annually? Yes ____ No ____

Do you have written procedures for preventative maintenance?. Yes ____ No ____

Does your hospital have a formal procedure for how to obtain a repair service? Yes ____ No ____

Do you provide a 24 hour on call service?. Yes ____ No ____

---oOo----

Does your department provide formal in-service training to offer other departments? Yes ____ No ____

During this year, did any department staff attend equipment training seminars at your hospital? Yes ____ No ____

in another city? Yes ____ No ____

Does your hospital provide a

continuing education programme? Yes ____ No ____

Is the department involved in equipment acquisition in the following areas?

	Yes	No
needs assessment	____	____
specification drafting	____	____
tender/proposal adjudication	____	____
incoming inspection	____	____

Are there areas of work that the department should be involved in but cannot because of the following reasons?

lack of staff	____	____
lack of budget	____	____
lack of floorspace/facilities	____	____

For the departments assigned responsibilities, are the following adequate:

staff	____	____
budget	____	____
floor space of facilities	____	____

Comments

....

....

....

....

....

....

THANK YOU FOR COMPLETING THIS SURVEY

B2. SURVEY ONE RETURNS

SURVEY OF FACILITIES, STAFFING & WAGES FOR CLINICAL ENGINEERING DEPARTMENTS IN HOSPITALS IN SOUTHERN AFRICA

Questionnaires sent: 250
received: 58

A. HOSPITAL DATA

1. --
2. --

3. Type of hospital

Private, non-profit	11	Private, for profit	5
Government	36	Other	0

4. Type of care/size/occupancy (% of replies)

short term	81	long term	56
general	78	special care	12
university based teaching hospital			10
other teaching hospital			5

number of beds
min: 30
ave: 328
max: 2740

5. Awareness of the discipline of clinical engineering before this survey.

Aware : 39 %
Unaware : 27 %

equipment repair and maintenance by:
in-house technical staff :48%
equipment suppliers :92%

B. DATA ON CLINICAL ENGINEERING DEPARTMENT (OR EQUIVALENT)

1. Is the clinical engineering department (or equivalent) a separate hospital department?

Yes 58% No 29%

2. **Department name**: (several given-- see discussion)

in house department: 42%
multi-hospital shared service: 11%
independent service vendor: 0%
Other: 0%

3. --

4. **Equipment services**

	Current Year	Last Year
Total no. of Devices Serviced	no returns	
Total Acquisition Value	ditto	

Areas in which department Services(% of returns)

Operating Theater	57	Clinical Labs	20
Recovery Room	49	Respiratory	31
CCU	23	ECG Service	46
ICU	26	EEC Service	23
Anaesthetics	40	Ultrasound/vascular	20
Obstetrics/Gynaecology	37	Radiology	34
Paediatric/Nursery	31	Radiation Therapy	14
Occupational Therapy	31	Burns Unit	14
Physiotherapy	34	Dental	26
Haemodialysis	31	Emergency/Trauma	18
General Medical	11	Office Automation	9
PABX/Communication	14	H.I.S./Computer centre	20
Medical Graphics /photography	14		

5. inconclusive returns
6. inconclusive returns
7. **Personnel**

	ave
no of artisans:	2,8
no of technicians:	5,0
no of support personnel:	3,8

8. inconclusive returns
9. inconclusive returns
10. inconclusive returns

11. **Departmental responsibilities(% of yes replies)**

quality assurance	28
hazard notification	21
dept.performance assessment	30
written policies and procedures	28
test equipment calibrated annually	23
preventative maintenance	19
formal repair service	33
24 hour on-call service	44

--oOo--

provide in-service training	7
attend training seminars	
. at hospital	12
. other city	9
continuing education	12

--oOo--

involvment in equipment acquisition:

. needs assessment:	33
. specification drafting:	33
. tender RFP adjudication:	29
. incoming inspection:	19

--oOo--

cannot be involved because of a lack of:

. staff	: 33
. budget	: 28
. floor space/facilities	: 23

for assigned responsibilities, are the following adequate:

	yes	no
. staff	19	3
. budget:	16	52
. floor space/facilities	28	11

APPENDIX C

C1. SURVEY TWO

SURVEY OF FACILITIES, STAFFING & WAGES FOR MEDICAL EQUIPMENT MANUFACTURERS/SUPPLIERS IN SOUTHERN AFRICA

The individual company and personnel data obtained in this survey will be kept strictly confidential. Please complete only one copy of this form for a single Medical Equipment Company. All information should be as of February 28, 1987. Please also have single copy of the accompanying INDIVIDUAL SALARY SURVEY form and return these with this or separately by June 30th, 1987 to: SURVEY DEPARTMENT, SAACE, PO Box 80, TYGERBERG, 7505.

A. COMPANY DATA

1. Name of company (optional)..............................

2. Street Address (optional)................................

City/Town .... Province/Country ....

Postal Code ....

3. Range of Equipment represented

Laboratory ____

Radiology ____

Nuclear Medicine ____

Ultrasound ____

Monitoring ____

Physio Therapy ____

Life Support ____

Surgical Instruments ____

General Medical ____

Other Specify

4. Approximate annual turnover ....

% by value produced locally............................

Value of spare parts kept ....

5. Distribution:

	Sales Centre	Service Centre	Head Office
Johannesburg	______	______	______
Durban	______	______	______
Cape Town	______	______	______
Port Elizabeth	______	______	______
Bloemfontein	______	______	______
Kimberley	______	______	______
Windhoek	______	______	______
Harare	______	______	______
Maputo	______	______	______
Other	______	______	______

6. Local Manufacture

(a) Spectrum of Involvement: (Fill in approximate % of total Business)

	Total Import	Partial Import	Local Assembly	Local Manu-facture	Local R & D	Export
Equipment						
Consuma-bles						
Reagents						

(b) Do you plan increased local manufacture?

No ____

if Yes, when:

Near future ____

Long term ____

7. Origin of imported equipment

Country	% of total
USA	
EUROPE	
JAPAN	
OTHER	

8. <u>Availability of technical personnel</u>

(a) Availability of suitably qualified technical staff:

easy to obtain _____

reasonably easy _____

difficult to obtain _____

(b) Do you consider the level of education adequate? (of personnel generally available at present in the job market today)

Yes _____ No _____

(c) Which of the following types of training do you provide for your technical staff?

basic (university or technicon) ....

on going ....

in service ....

factory ....

none ....

9. <u>Relationship to hospitals</u>

(a) Do you consider clinical engineering staff at hospitals:

- detrimental to your business interests
- a boon to your business interest
- of no influence on your business interests
- very competent
- reasonably competent
- incompetent

(b) Would you prefer:

- to do all repairs of your equipment at hospitals?
- permit hospital staff to perform minor repairs and maintenance?
- hospital staff to perform all repairs and maintenance?

(c) Are you in favour of service agreements with hospitals?

Yes ______ No _____

If yes, which type of agreement do you prefer?

- time and materials ...._____
- regular preventative maintenance service with in between callouts at time and material charges..........................._____
- comprehensive, all inclusive contracts with fixed annual cost _____

(d) Would you be prepared to provide training to hospital technical staff:

	Yes	No
- first line maintenance	_____	_____
- full factory level training	_____	_____

(e) Do you frequently recruit staff from hospitals?

Yes ____ No ____

- Do you frequently lose staff to hospitals?

Yes ____ No ____

B. CLINICAL ENGINEERING (SERVICE, TECHNICAL ETC) DEPARTMENT DATA

1. Is the clinical engineering department (or equivalent) a separate company department.

Yes ____ No ____

If yes, to what other department or individual in your company does it report to?

....

If no, what other department or function is it part of?

....

2. Department Name

in house dept. _____ other company _____

3. * Name of dept. head *Phone.......

* Title ....

*Optional for possible follow up contact.

4. Floor space

	Actual	Planned
Active floor space	....	....
+ Passive storage space	....	....
= Total departmental floor space	....	......

5. Test Equipment

Please include all electrical test equipment, computers, safety testers, mechanical equipment, tools and other instrumentation owned by this department.

	Actual	Planned
Total Dept. equipment	R...........	R...........

6. Personnel

(Please use the job descriptions given at the end of this survey)

	Actual	Planned
No of Artisans + No of Technicians + No of Engineers + Support Personnel = Total personnel	....	....
Vacant positions (not included in above)	....	....

7. Salary Ranges (before deductions)

	Min. R/annum	Max. R/annum
Artisans	....	....
Technician	....	....
Sen. tech	....	....
Technician supervisor	....	....
Engineer	....	....
Department head	....	....

8. <u>Annual budget for clinical engineering department (or equivalent)</u>

	1986	1987
Salaries	....	....
+ repair material/ spare parts	....	....
+ supplies	....	....
+ Outside services	....	....
+ Capital & test equipment	....	....

9. <u>Computer equipment</u>

(List only computer equipment available for use by or dedicated to this department)

Mini computer (type) .... (quantity)...........

Micro computer (type) .... (quantity)...........

Is software operational for:

Preventative maintenance scheduling Yes _____ No _____

Service history database Yes _____ No _____

Labour & timekeeping/billing Yes _____ No _____

Spares inventory Yes _____ No _____

Accounting Yes _____ No _____

Management reporting Yes _____ No _____

Access to databases (via data comms) Yes _____ No _____

CAD (computer aided drafting) Yes _____ No _____

THANK YOU FOR COMPLETING THIS SURVEY

C2. SURVEY TWO RETURNS

SURVEY OF FACILITIES, STAFFING AND WAGES FOR MEDICAL EQUIPMENT MANUFACTURERS/SUPPLIERS IN SOUTHERN AFRICA

(number of replies, unless otherwise indicated)

Questionnaires sent: 150
received: 7 %returns = 4,7%

A. **COMPANY DATA**

3. **Range of equipment represented**:

Laboratory	3	
Radiology	0	
Nuclear Medicine	0	
Ultrasound	3	
Monitoring	3	
Physiotherapy Therapy	2	
Life Support	4	
Surgical Instruments	4	
General Medical	4	
Other	4	Theater apparatus Single use devices Sterilization Equipment Orthopaedic implants Furniture Ophthalmic equipment

4. Approximate annual turnover
% by value produced locally
Value of spare parts kept
note: no comments received--information considered confidential.

5. **Distribution**

	Sales	Service Centre	Head Office
Johannesburg	7	6	7
Durban	7	6	
Cape Town	7	6	
Port Elizabeth	4	0	
East London	1	0	
Bloemfontein	4	2	
Kimberley	0	0	
Windhoek	3	1	
Harare	1	0	
Maputo	0	0	

6. **Local manufacture**

a) Returns could not be processed.

b) Increase in Local Manufacture Planned

Yes 5 No 2

if,yes:

Near future: 3

Long term : 2

7. **Origin of imported equipment**

Country	Average % of total
USA	50
EUROPE	50
JAPAN	20
OTHER	10

8. **Availability of technical personnel**

(a) Availability of suitable qualified technical staff:

.Easy to obtain	0
.Reasonably easy to obtain	1
.Difficult to obtain	5

(b) Adequacy of level of education of personnel generally available at present in the job market

Yes 5 No 1

(c) Types of training provided for technical staff:

Basic (University or technicon)	2
On going	4
In service	5
Factory	1

9. **Relationship to hospitals**

(a) clinical engineering staff at hospitals considered as:

.detrimental to business interests	1
.boon to business interests	3
.no influence on business interests	1

or

.very competent	0
.reasonably competent	3
.incompetent	1

(b) Preference to

.do all repairs of equipment at hospitals	1
.permit hospital staff to perform minor repairs and maintenance	5
.hospital staff to perform all repairs and maintenance	1

(c) Service agreements with hospitals
Yes: 5 No: 1

Type of agreement:

.time and materials	0
.regular preventative maintenance service with in between call outs at time and material charges	3
.comprehensive, all inclusive contracts with fixed annual costs	2

(d) Providing Training to hospital technical Staff:

	Yes	No
.first line maintenance	6	0
.full factory level training	2	3

(e) Frequent recruiting of staff from hospitals
Yes: 1 No: 5

Frequent losing staff to hospitals
Yes: 0 No: 6

B. CLINICAL ENGINEERING (SERVICE,TECHNICAL ETC) DEPARTMENT DATA

1. no returns
2. ditto
3. ditto
4. Floor space
   total actual floor space: 60-800, ave=325 sq. m.

5. Test equipment
   R20-100 000, ave=R40 000

6. Personnel

	range	average
artisans		4
technicians	2 - 9	4,2
engineers	1 - 3	1,8
support personnel	2	2
TOTAL:	1 - 11	6

7. Salary ranges

	min x R1000/annum		max x R1000/annum	
		ave		ave
artisans	23	23	28	28
technicians	12 - 26	15	24 - 32	28
sen. techn.	28	28	30	30
tech. super	45 - 75	60	60	60
engineer	30 - 55	40	40 - 70	50
dept. head	45	45	60	60

8. Annual Budget

no returns

9. Computer equipment

computers available: nil

software operational:

. preventative maintenance scheduling	0
. service history database	0
. labour & timekeeping	0
. spares inventory	1
. accounting	3
. management reporting	1
. external databases	0
. CAD(drafting)	0

APPENDIX D

D1 SURVEY THREE

SALARY SURVEY FOR INDIVIDUAL CLINICAL ENGINEERS AND TECHNICIANS IN SOUTHERN AFRICA

The individual data obtained via this survey will be kept strictly confidential. All data will be aggregated for statistical purposes. Please copy this sheet and have all departmental Clinical Engineers and Technicians complete this form individually. These individual sheets may be completed in conjunction with the hospital/company survey or may be returned separately. Each person should only submit one individual form. Information should be as of February 28, 1987. Please return this form before June 30th, 1987 to: Survey Dept., SAACE, P.O. Box 80, Tygerberg, 7505.

PLEASE DUPLICATE & DISTRIBUTE THIS FORM TO ALL APPROPRIATE TECHNICAL PERSONNEL

A. 1. Your name (optional) ....

2. Hospital/company ....

City/Town .... Province/country ....

Postal code ....

No of beds (if working for hospital) ....

3. Title of your position

(If possible please use the closest generalised job title selected from the descriptions in the attached appendix).

4. Your age .... (years) Sex: Male _____ Female _____

5. Your total years of experience in this position in-cluding all related prior experience in the same or lesser positions. (All experience counted should be in the general field of clinical engineering and technology).

Total years .... Years with present hospital/company ....

6. Qualifications

(a) None_____ N3_____ N6_____ T3_____

NTC_____ B.Sc_____ M.Sc_____ PhD_____

Other (explain) ....

(b) Registration: Engineering technician _____

Engineering technologist _____

Professional engineer _____

(c) Which professional societies are you a member of? (e.g. SAACE, SAIEE):

7. Present position

Number of people your supervise? ....

Your gross starting salary at this Organisation? R/yr: ....

Your present gross salary at this Organisation? R/yr: ....

Your gross salary last year? R/yr: ....

(Gross salary is before deductions and includes benefits)

8. Job responsibilities

Please indicate what percentage (%) of your time is spent on each of the following tasks during a typical month (total 100%, please).

Repairs	____	Purchasing/ requisitions for Dept.	____
Design & modification of instruments	____	Supervision/administration	____
Research	____	Giving training/in service	____
Safety testing	____	Receiving training	____
Preventative Maintenance	____	Department development	____
Incoming Device/ testing/ installation	____	Service to outside organisations	____
Prepurchase evaluations/ consultations	____	Safety committee	____
Other	____	Other	____
Other	____	Other	____

9. <u>Computers</u>

(a) Do you have access to computers?

at work ____ at home ____ other (specify) ....

micro ____ mini ____ mainframe ____

(b) How do you rate the following software packages/ tools for your work? (typical package names given in brackets)

	is being used	could be useful	not familiar with
- word processing (Wordstar, MS Word Etc)			
- database (dBase III etc)			
- spread sheet (Lotus)			
- graphics (Chart)			
- project management (superproject)			
- computer aided drafting (Autocad)			
- measurement and analysis (Assyst)			
- expert systems (Exsys)			
- PCB design (Smartwork)			

10. Which of the following journals do you read regularly?

Journal of Clinical Engineering ____

Medical Instrumentation (AAMI Journal) ____

IEEE Journal of Engineering in Medicine and Biology ____

Journal of Medical Technology ____

Clinical engineering Newsletter ____

Biomedical Safety and Standards Newsletter ____

Hospitals (A.H.A. Journal) ____

Byte ____

Electronic Design ____

Pulse ____

Dataweek ____

Other ....

Other ....

11. Based on your work experience, in which of the following areas would you have liked more training?

	included in basic education	in-service training
- medical instrumentation theory - computer theory - data communications - speech techniques - writing techniques - physiology and anatomy - hospital administration - accounting/finance - other		

D2 SURVEY THREE RETURNS

SALARY SURVEY FOR INDIVIDUAL CLINICAL ENGINEERS AND TECHNICIANS IN SOUTHERN AFRICA

Questionnaires sent:250
received: 78 (% returns = 31,2 %)

1. --
2. **Number of beds**
   min: 30
   ave: 803
   max: 2756
3. --
4. **Age of respondees**
   min: 21
   ave: 42
   max: 66

5. **Total years of experience:**
   (with present company/hospital)
   min: 1
   ave: 8,5
   max: 30

6. **Qualifications**

(a)

None	11	N3	31	N6	3	T3	10
NTC	0	B.Sc	4	M.Sc	2	PhD	0

Other: tradesmen=5

(b) Registration
Engineering Technician :23
Engineering Technologist : 2
Professional Engineer : 1

(c) Member of professional societies
SAACE :28 SAIEE : 5 Other : 3

7. **Present position**
   Number of people supervised
   min: 1
   ave: 18
   max:300
   Gross starting salary R x 1000/yr:
   min: 1,2
   ave:13,2
   max:49,1
   Present gross salary R x 1000/yr:
   min: 7
   ave:28,6
   max:71,5

8. Job responsibilities

Percentage of time spent on each of the following tasks during a typical month:

Repairs	39,5	Purchasing/requisitioning for Department	5,5
Design & modification of instruments	2,9	Supervision/administration	13,9
Research	1,4	Giving training	3,58
Safety testing	4,4	Receiving training	1,6
Preventative maintenance	8,0	Department development	1,78
Incoming testing & installation	2,46	Service to outside organisations	1,73
Prepurchase evaluations/ consultations	1,67	Safety committees	1,38
Other	1,9		

9. Computers

(a) Access to computers

at work:	19	at home:	8	other:	0
micro:	19	mini:	4	mainframe:	2

(b) Rating of software packages

	is being used	could be useful	not familiar with
word processing (Wordstar,MS Word etc.)	10	5	14
database (dBase III etc.)	8	6	14
spread sheet (Lotus)	6	3	15
graphics (MS-chart)	4	9	15
project management (Superproject)	1	7	16
computer aided drafting (Autocad)	0	10	14
measurement and analysis (Assyst)	3	7	15
expert systems (Exsys)	0	4	20
PCB design (Smartwork)	3	11	10

10 **Journals**

Journal of Clinical Engineering	15
Medical Instrumentation (AAMI Journal)	7
IEEE Journal of Engineering in Medicine and Biology	1
Journal of Medical Technology	3
Clinical Engineering Newsletter	17
Biomedical Safety and Standards Newsletter	6
Hospitals (A.H.A. Journal)	16
Byte	2
Electronic Design	9
Pulse	16
Dataweek	15
Other	6

11..**Based on work experience, areas that need more training**

	included in basic education	in-service training	neither
medical instrumentation theory	4	27	34
computer theory	10	6	54
data communications	3	5	67
speech techniques	4	1	70
writing techniques	6	2	68
physiology and anatomy	8	11	52
hospital administration	4	8	59
accounting/finance	2	2	72
other	0	3	75

APPENDIX E

This document was handed to interviewees to provide them with an overview of the ICE department that they could study attheir leasure after the interview.

THE IDEALISED CLINICAL ENGINEERING DEPARTMENT: AN OVERVIEW

E1. Introduction

Clinical engineering was first established in 1965 as the "application of systems engineering to health-care with the aim to optimize the safety, effectiveness, efficiency and economy of health-care technology" (Caceres 1978). Over the past three decades much experience has been gained at different centres worldwide. This overview of the idealised clinical engineering department (ICE) represents the collection of these experiences as described at the annual congresses of the Association for the Advancement of Medical Instrumentation (AAMI, 1984).

The idealised clinical engineering department (ICE) consists of personnel, infrastructure and facilities. These are arranged in a number of interrelated systems designed to provide and support health-care technology optimally for the hospital concerned. This overview will briefly describe these systems and their rationale.

E2. Fundamental concepts

E2.1 Complexity - the team approach

Technology in health-care has become extremely complex. Principles from many disciplines are employed: physiology, chemistry, ergonomics, software engineering, electronics, computer science and applied mechanics, to name but a few. Since no single individual can be proficient in all these areas, a team approach is indicated. The ICE therefore consists of a team of people with expertise in specialised areas. The ICE also has the management capability to employ expertise external to itself either in the hospital or in outside organisations.

The resulting organisational structure should therefore be based on matrix management.

E2.2 ICE Systems

a) support for technology life cycle

In general the introduction of commercially available technology to an organisation follows a certain pattern or life cycle. This life cycle consists of a number of phases:

- planning
- acquisition
- commissioning
- support
- replacement

The ICE consists of integrated systems to support each of these phases.

b) <u>support for research</u>

The conversion of the results of research into commercially available technology also has a number of phases, some of which could take place within the hospital. The ICE has <u>systems</u> to support these as well.

c) <u>support for planning</u>

Hospitals are experiencing increased demands for their services and limited resources. In addition, the life cycle of technology is becoming shorter. To be able to cope, strategic planning has become imperative. The ICE provides systems to support the hospital's planning effort (operations research, systems analysis etc) and systems to implement the technology elements of the resulting plans (project management etc).

E2.3 <u>Information - a key resource</u>

To manage technology optimally implies access to information. The ICE must have an information system to support it. There must also be access to national and international data bases and indexes related to technology reviews, hazards, standards, evaluations, developments and related matters.

E2.4 <u>ICE - external relationships</u>

The ICE cannot function in isolation. It must relate to other groups both within and external to the hospital. Each of these groups has a specific role to fulfil but must operate synergistically. These relationships are shown diagrammatically below:

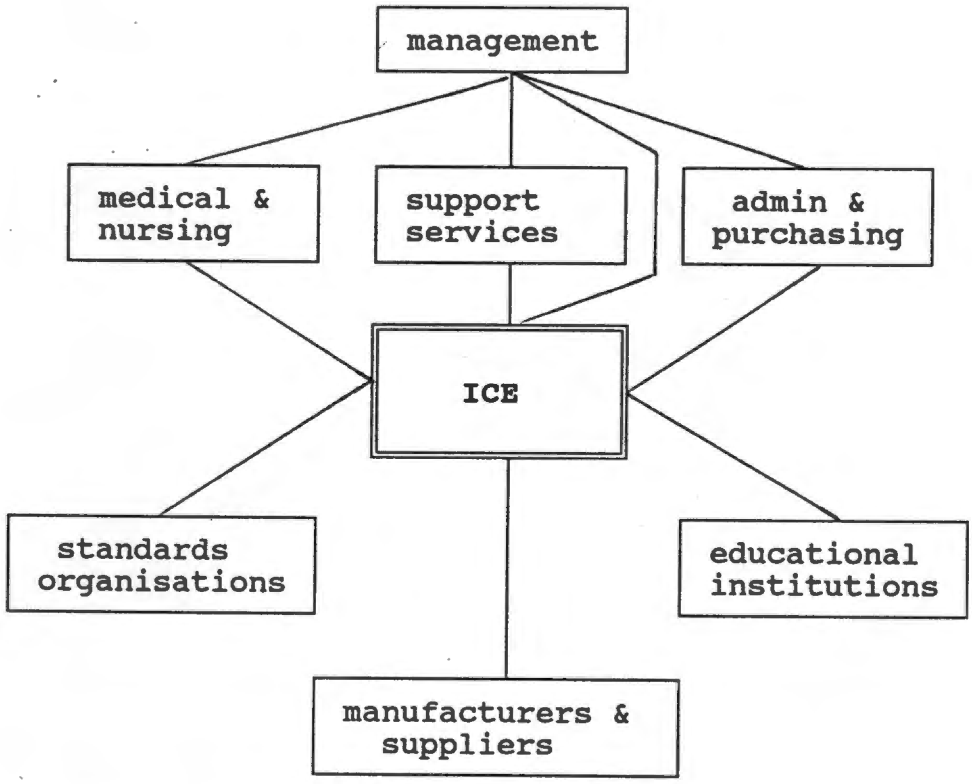

Figure E1 ICE-external relationships

E2.5 Staff competence

The ICE presupposes the availability of appropriately-trained competent staff to ensure efficiency and compliance with medico-legal requirements. The ICE must ensure that its personnel are and remain competent by:

- co-operation in the international Clinical Engineering certification programme run by the International Certification Commision
- in-service continuing education
- appropriate training at educational institutions.

E2.6 <u>ICE scope</u>

The ICE presented here is appropriate for a large tertiary care hospital that is also active in a wide spectrum of research and teaching. The infrastructure and personnel contingent for other types of hospitals would be a subset of the total presented here. The scope of the ICE for any particular hospital is determined by its

- goals and objectives (mission)
- size (number of beds)
- level of technology (number of special care units)
- geographical location.

Based on international norms (Johnston, 1985) typical establishments would be:

-	100 bed country hospital : 1 x technician with 30 meters^2 floorspace
-	200 bed country hospital : 4 x technicians, 1 engineer and 70 meters^2 floorspace
-	1000 bed teaching hospital:22 technicians, 5 engineers and 1 000 meter^2 floorspace.

E3. <u>ICE systems</u>

The ICE infrastructure is divided into a number of major systems or functions as follows:

Technology life cycle	ICE systems
1. Planning phase	Needs analysis, value analysis, strategic planning, operations research, facilities planning, research and development.
2. Aquisition phase	Equipment evaluation, specification drafting, or request for proposal preparation, tender adjudication.
3. Commissioning phase	Incoming inspection, installation, project management, user training.
4. Support phase	Repair, preventative maintenance, calibration, contract administration, modification, call-out, safety and standards, in-service training.
5. Replacement	Life cycle costing, disposal.

E4. The ICE infrastructure

E4.1 Technical sections

The infrastructure is organised around a collection of specialised technical sections each with its corresponding laboratory or workshop. Each technical section is responsible for the support of a subset of the hospital's equipment that falls within its particular specialisation. Specialisation areas include:

- fine optics
- theatre instruments
- xray and imaging systems
- laboratory equipment and systems
- general electronics
- quality control
- respiratory and anaesthetic equipment
- sterilisation systems
- telecommunication equipment (pagers, PEBX, nurse call, intercoms)
- computers and data communications
- information systems
- audiovisual, television, photographic and graphics equipment
- machine shop (metal, wood, perspex)
- office equipment and systems
- drawing office

E4.2 Projects

A part of the capacity of the technical sections is used for

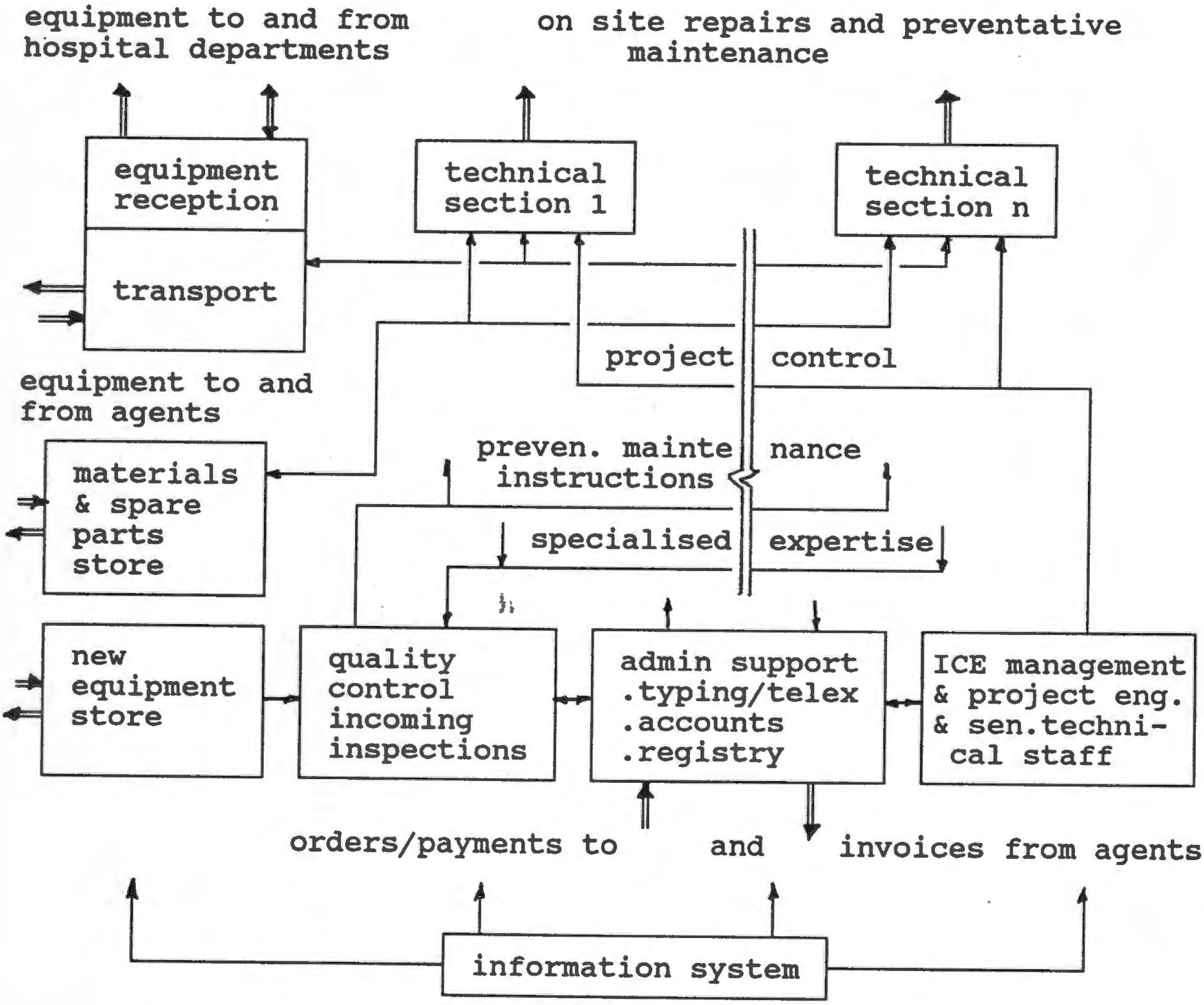

Figure E2 A typical clinical engineering infrastructure

the routine support of technology (repairs, maintenance). The remainder of the capacity is allocated for projects such as modifications, research and development, commissioning and so on. The projects are controlled by the projects management system.

E4.3 Administrative support

The ICE is effectively a business organisation and must have administrative support services such as typing, filing and accounting.

E4.4 Logistic support

Depending on the size and geographical location of the hospital, the ICE will require a spare parts and materials store and transport facilities.

E4.5 Information system and documentation support

Information is essential to the ICE for planning, management and medico-legal requirements. A computerized information system is imperative. The computer system must also provide for the scientific programming needs of the ICE. A generic computer system is shown in figure E3 based on local area network technology.

As much of the ICE's output is in the form of reports, plans, charts, labels, drawings, specifications and circulars, powerful text processing and graphics facilities are required. These should include output onto video, 35mm slides and overhead projector transparencies.

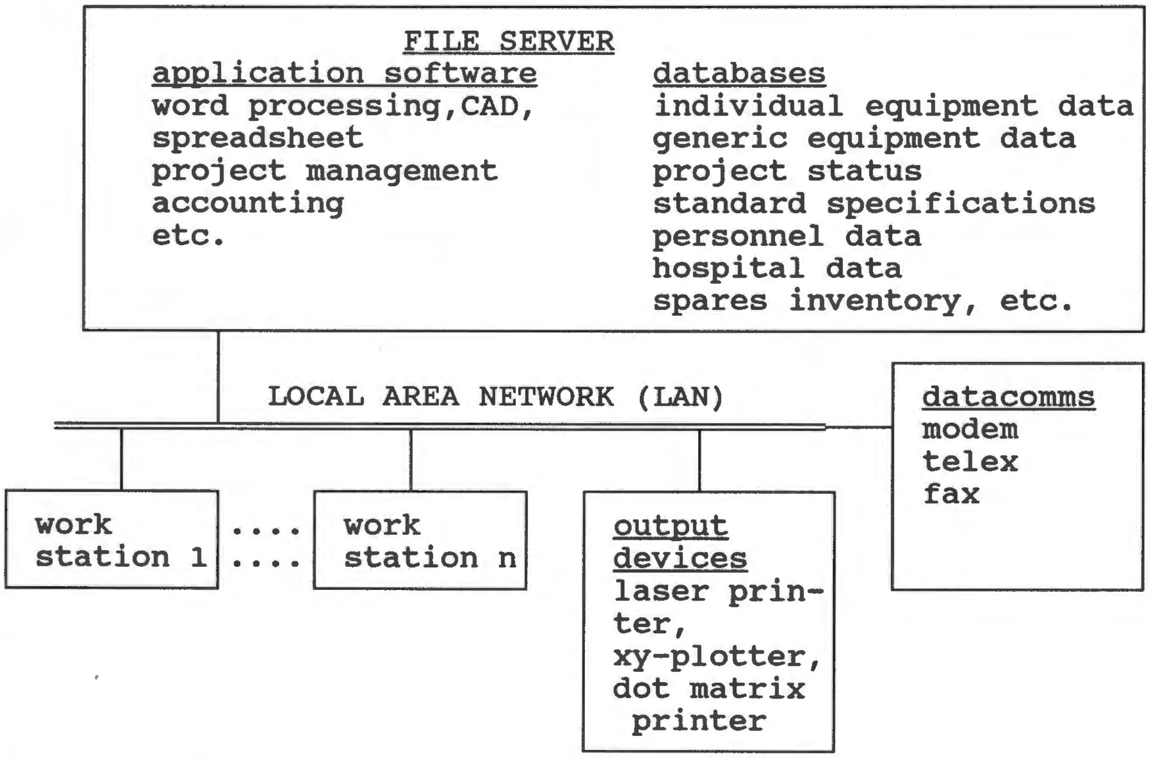

Figure E3 The decision support system hardware

E4.6 Smaller hospitals

In smaller hospitals it is not cost effective to have the full spectrum of technical sections. A smaller selection appropriate for the hospital (perhaps only a mechanical and an electronic section) is required.

As the technical staff would then cover more specialities, they would have to be wider qualified. The work that they cannot handle could be contracted out.

E5. Staffing norms

Although there are large variations from organisation to organisation, average norms (Judd, 1983, Johnston, 1985) are as follows:

E5.1 Teaching hospitals and high care hospitals

11 instruments/bed - 500 instruments/technician,
4 technicians/engineer.

E5.2 Large hospitals

7 instruments/bed - 500 instruments/technician,
6 technicians/engineer.

E5.3 Small hospitals

4 instruments/bed - 600 instruments/technician.

E6. Bibliograhpy

1. Caceres C. 1978: The practice of clinical engineering.

2. AAMI. 1983 - 1985: Special sessions on clinical engineering in the proceedings of the 18th, 19th and 20th Annual Meetings of the Association for the Advancement of Medical Instrumentation.

18th Meeting:

- Clinical engineering risk management
- Clinical engineering profession - need for an expanded definition
- The diversity of clinical engineering approaches to hospital technological problems
- Clinical engineering management
- Innovations in promoting the clinical engineering function in the hospital environment

19th Meeting:

- Clinical engineering: Opportunities in a changing health-care delivery system.
- Worldwide growth and development of clinical engineering.
- New frontiers in clinical engineering.
- New dimensions in clinical engineering.

20th Meeting:

- Clinical engineering management success stories.
- Clinical engineering education.

3. Johnston, I. 1985: A maintenance model for clinical engineering. IEEE Eng Med Biol;. June 85 Vol. 88:19 - 24.

APPENDIX F

F1. SURVEY FOUR

ACCEPTABILITY OF THE IDEALISED CLINICAL ENGINEERING DEPARTMENT MODEL TO HEALTH-CARE PROFESSIONALS

The individual data obtained via this survey will be kept strictly confidential. All data will be aggregated for statistical purposes.

A. Respondee information

1. Current position

- hospital medical superintendent ___
- health-care administration manager ___
- other (specify) ....
- location of your organisation (city)

....

2. Qualifications

- basic: ....
- post graduate (eg MBA):..................

3. Related experience

Have you had personal experience:

	Yes	No
- as a hospital superintendent	____	____
- hospital planning	____	____
- equipment acquisitioning	____	____
- court cases resulting from equipment-related accidents	____	____

4. <u>Description of idealised clinical engineering (ICE) Model</u>

	Yes	No
- Was the description easy to understand/comprehensive	____	____
- Are you familiar with:		
- matrix management	____	____
- strategic planning	____	____
- project management	____	____
- operations research	____	____
- systems engineering	____	____

As an overall impression would you consider that the ICE would:

- satisfy real needs	____	____
- be implementable	____	____
- be too expensive	____	____
- be acceptable to medical staff	____	____
- be acceptable to administration staff	____	____
- be acceptable to nursing staff	____	____

5. <u>ICE details</u>

Please give your opinion about the following aspects of an ICE

5.1 Systems

	essen-tial	useful	not re-quired	unknown
Planning				
Need analysis				
Value analysis				
Strategic planning				
Facilities planning				
Research and deve-lopment				
Acquisition				
Equipment evaluation				
Specification drafting				
Tender and RFP preparation				
Tender and RFP adjudication				
Commissioning				
Incoming inspection of newequipment				
Installation				
Project management				

	essen-tial	useful	not re-quired	unknown
<u>Support</u>				
Repair, cali-bration				
Preventative maintenance				
Contract administration				
Design and modification				
Call-out (standby)				
Safety and standards compliance				
In-service training				
<u>Replacement</u>				
Life cycle costing				
disposal				

5.2 Technical sections

	essen-tial	useful	not re-quired	unknown
Fine optics				
Theatre instruments				
Xray/ultrasound and imaging				
Laboratory equip-ment/systems				
General electronics				
Quality control				
Respiratory and anaesthetics				
Sterilization equipment				
Telecommuni-cations				
Computers and data com-munication				
Information systems				
Audiovisual, television, photography and graphics equip.				
Office equipment and systems				
Machine shop (wood, perspex, metal)				
Drawing office				

5.3 Infrastructure

	essen-tial	useful	not re-quired	unknown
Project management				
Admin support				
Logistic support				
Information system				
Text processing				

5.4 Staffing norms

	Too high	adequate	Too low	Don't know
Teaching hospitals				
Large hospitals				
Small hospitals				

6. General comments

....

....

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THANK YOU FOR COMPLETING THE SURVEY. PLEASE RETURN IT TO THE ADDRESS ABOVE. WATCH FOR THE RESULTS IN THE SOUTH AFRICAN MEDICAL JOURNAL.

F2. SURVEY FOUR RETURNS

ACCEPTABILITY OF THE IDEALISED CLINICAL ENGINEERING DEPARTMENT MODEL TO HEALTH-CARE PROFESSIONALS

Questionnaires sent:25
received:11 (44%)

A. **RESPONDEE INFORMATION**

1. **Current position**

hospital medical superintendent	3
health-care administration manager	7

2. **Qualifications**

Basic:	Medical	5
	Administrative	2
	Nursing	1
Post graduate (eg. MBA):		3

3. **Related experience**

	Yes	No
as a hospital superintendent	8	3
hospital planning	11	0
equipment acquisitioning	9	2
court cases resulting from equipment-related accidents	3	8

4. **Description of idealised clinical engineering (ICE) model**

	Yes	No
Was the description easy to understand	11	0
Familiar with:		
.matrix management	6	5
.strategic planning	9	2
.project management	9	2
.operations research	4	7
.systems engineering	4	7
Overall impression:		
.satisfy real needs	9	2
.implementable	11	0
.too expensive	5	6
.acceptable to medical staff	9	2
.acceptable to administrative staff	9	2
.acceptable to nursing staff	9	2

5. **ICE details**

5.1 **Systems**

	Essential	Useful	not Necessary	Don't know
Planning				
Needs analysis	8	2	1	0
Value analysis	8	2	1	0
Strategic planning	8	2	1	0
Facilities planning	8	2	1	0
Research and development	3	5	3	0
Acquisition				
Equipment evaluation	8	3	0	0
Specification drafting	8	3	0	0
Tender and RFP preparation	8	3	0	0
Tender and RFP adjudication	8	3	0	0
Commissioning				
Incoming inspection of new equipment	8	2	1	0
Installation	9	1	1	0
Project management	9	2	0	0
Support				
Repair calibration	10	0	1	0
Preventive maintenance	9	1	0	1
Contract administration	8	2	0	1
Design and modification	7	4	0	0
Call-out (standby)	10	0	0	1
Safety and standards compliance	10	0	0	1
In-service training	9	2	0	0
Replacement				
Life cycle costing	8	3	0	0
Disposal	6	4	0	1

5.2 **Technical sections**

	Essential	Useful	Not required	Unknown
Fine optics	6	4	1	0
Theatre instruments	7	4	0	0
Xray/ultrasound and imaging	8	2	1	0
Laboratory equipment/ systems	8	3	0	0
General electronics	9	1	1	0
Quality control	7	3	1	0
Respiratory and anaesthetics	10	0	1	0
Sterilization equipment	9	1	1	0
Telecommunications	6	3	2	0
Computer and data communication	6	3	2	0
Information systems	5	4	2	0
Audiovisual, television, photography and graphics equipment	4	5	2	0
Office equipment and systems	5	4	2	0
Machine shop (wood, perspex, metal)	7	3	1	0
Drawing office	5	4	2	0

5.3 **Infrastructure**

Project management	8	3	0	0
Admin support	8	2	1	0
Logistic support	8	2	1	0
Information system	7	3	1	0
Text processing	2	7	2	0

5.4 **Staffing norms**

	Too high	Adequato	Too Low	Don't Know
Teaching hospitals	4	4	0	3
Large hospitals	2	8	0	1
Small hospitals	2	6	1	2

APPENDIX G

G1. SURVEY FIVE

ACCEPTABILITY OF THE IDEALISED CLINICAL ENGINEERING DEPARTMENT MODEL

TO MEDICAL EQUIPMENT SUPPLIERS

The individual data obtained via this survey will be kept strictly confidential. All data will be aggregated for statistical purposes.

A. RESPONDEE INFORMATION:

1. Current position in your company

- management ____
- medical equipment sales ____
- technical support ____
- other (specify) ____
- location of your organisation (city) ____

2. Qualifications

- basic ....
- post graduate (eg MBA) ....

3. <u>Related experience</u>

Have you had personal experience in/of

	Yes	No
-training equipment users	____	____
- administrating service agreements	____	____
- planning medical systems	____	____
- court cases resulting from equipment-related accidents	____	____

4. <u>Description of idealised clinical engineering (ICE) Model</u>

	Yes	No
- Was the description easy to understand/comprehensive	____	____
- Are you familiar with:		
- matrix management	____	____
- strategic planning	____	____
- project management	____	____
- operations research	____	____
- systems engineering	____	____

As an overall impression would you consider that the ICE would:

	Yes	No
- satisfy real needs	____	____
- be implementable	____	____
- be too expensive	____	____
- be acceptable to medical staff	____	____
- be acceptable to	____	____
administrative staff	____	____
- be acceptable to nursing staff	____	____

What impact would ICE have on your company:

	Yes	No
- of general benefit	____	____
- useful only at some hospitals	____	____

if yes, which?

- teaching hospital _____
- large hospital _____
- small hospital _____
- country hospital _____

	Yes	No
- useful only in some aspects	____	____

if yes, which?

- sales _____
- repairs _____
- preventative maintenance _____
- user training _____
- other _____

	Yes	No
- a general threat to your business interests	____	____

5. Staffing norms

	too low	adequate	too high	don't know
Teaching hospitals				
Large hospitals				
Small hospitals				

6. General comments

....

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THANK YOU FOR COMPLETING THE SURVEY. PLEASE RETURN IT TO THE ADDRESS ABOVE. WATCH FOR THE RESULTS IN THE SOUTH AFRICAN MEDICAL JOURNAL.

G2. SURVEY FIVE RETURNS

ACCEPTABILITY OF THE IDEALISED CLINICAL ENGINEERING DEPARTMENT MODEL TO MEDICAL EQUIPMENT SUPPLIERS

Questionnaires sent: 25
received : 10 (40%)

A. **Respondee information**:

1. **Current position in company**:

Management	6
Medical equipment sales	5
Technical support	3

2. **Qualifications**:

Basic:	Matric	7
	Technical	5
Post graduate (eg. MBA):		3

3. **Related Experience**:

	Yes	No
Training equipment users	9	0
Administering service agreements	6	3
Planning medical systems	5	4
Court cases resulting from equipment-related accidents	1	7

4. **Description of idealised clinical engineering (ICE) model**

	Yes	No
Description easy to understand, comprehensive	10	0
Familiar with:		
.matrix management	8	2
.strategic planning	9	1
.project management	9	1
.operations research	7	3
.systems engineering	6	4
Overall impression, would ICE:		
.satisfy real needs	9	1
.be implementable	8	2
.be too expensive	3	7
.be acceptable to medical staff	8	1
.be acceptable to administrative staff	7	2
.be acceptable to nursing staff	7	2

ICE impact on companies

.of general benefit		8	1
.useful only at some hospitals		6	3
if Yes, which:			
teaching hospitals	5		
large hospitals	5		
small hospitals	2		
country hospitals	1		
.useful only in some aspects		4	5
if Yes, which			
sales	0		
repairs	3		
preventative maintenance	4		
user training	3		
other	0		
.a general threat to your business interests		1	9

5. **Staffing norms**

	too low	ade-qua-to	too high	don't know
Teaching hospitals	2	2	2	4
Large hospitals	0	4	2	4
Small hospitals	1	3	2	4

APPENDIX H

H1 SURVEY OF COMMERCIAL SOFTWARE FOR POSSIBLE APPLICATION IN THE DSS OF IDEALISED CLINICAL ENGINEERING MODEL

H1.1 Clinical engineering (equipment management)

Software package	Supplier
Micro (single user)	
Aims	Michigan Hosp.Assn.
J-Trak	Bio-Sentry Inc.
Altman's BME Database	Quest Publishing
MMS	UNIK Corp.
McDECS	Integral Biomedical Engineering Co.
Seabord	Seabord
HEMS	Medical Instrumentation Systems
MAC	Maintenance Automation
ATS	Auto Till Services
American	AMSCO Corp.
Clinical Equipment	Turn Key Micro
Record Keeping System	
HECS	ECRI Corp.
Master Maintenance Management System	Software Programming Corp
Med Pac	CSI Data Services Inc.
Micro (Multi-user (LAN))	
Clinical equipment record keeping systems	Turn Key Micro
PM	Context
CEMS	Savant Corp.
Med Pac	CSI Data Services Inc.

Table H1 Commercial equipment control software for clinical engineering

Software package	Supplier
Mini computers	
CEMS	Savant Corp.
Computer equipment maintenance system	ISA
M Cubed	Sun Health Inc.
AEMS	V.A. Hospitals
Main frames	
M Cubed	Sun Health Inc.
CEMS	Savant Corp.
PM AS/TEC	Werner and Assoc.
National Clinical Engineering computer network	ECRI/Booing Corp.
MEMS	Stoney Brook Hospital
SHEMS	Sinai Hospital

Table H1(cont.) Commercial equipment control software for clinical engineering

H1.2 Decision support systems

Package name	Type	Supplier
Arborist	Decision tree	Texas Instruments
The Confidence Factor	Monte Carlo, decisiontree, decision matrix, linear programming	Simple Software Inc.
Decision	matrix	Once Begun
Decision Aide	Decision matrix	Kepner Tregoe Inc.
Decision Modeling	Decision matrix	Ashton Tate
Expert Choice	Decision matrix /tree	Decision Support
Light Year	Matrix	Thoughtware Inc.
Predict!	Monte Carlo	Unison Technology
Prism	Monte Carlo	Tempus Decelopment Corp.
What's Best	Linear programming	General Optimisation Inc.
GPSS/PC	Simulation	Minuteman Software
Siman PC	Simulation	Systems Modelling Corp.
SLAM PC	Simulation	Pritsker and Assoc.
Lotus 123	Spreadsheet	Lotus Corp.
Framework	Spreadsheet	Ashton Tate
MS-Excel	Spreadsheet	Micro Soft
SAS-System	Spreadsheet statistics, graphics	SAS Institute

Table H2 Decision support software packages for personalcomputers.

H1.3 Project management

Package name	Supplier
MS-PROJECT	Micro Soft Corp.
Harvard Project	Harvard Software
Timeline	Breakthrough Software
Instaplan	Instaplan Corp
Primavera project planner	Primavera Systems

Table H3 Project management software packages

H1.4 WINDOWS-based packages

Package name	Type	Supplier
Nexpert Object	AI expert system	Neuron Data
Page Maker	Desktop publishing	Aldus Corporation
Omnis QUARTZ	Multi-user database	Blyth Software
Network Courier	Electronic mail	Consumers Software
Windows DRAW	Presentation graphics	Micrografx
PC Paintbrush	Colour graphics design	Z Soft Corp
Click Start!	Application .organiser	LDC computer Corp
Windows GRAPH	Business graphics/ charting	Micrografx
Dragnet	Text retrieval	Access Softek
In *a* Vision	CAD	Micrografx
Windows Mail	Electronic Mail	Da Vinci Systems
MS Excel	Spreadsheet	Microsoft Corp.
Scrapbook	Art images	T/Maker Company
Page view	Page preview for word processing	Microsoft Corp.

Table H4 Available software packages for WINDOWS user interface environment

H1.5 Integrated software

	Package name Supplier
Smartware	Innovative Software
Enable	The Software Group
Open Access	Software Products Inc.
Frame work	Ashton Tate
MS-Works	Microsoft Corporation
Symphony	Lotus Corp.

Table H5 Integrated software packages (Database, word processing, spreadsheets, graphics and data communications)

H1.6 Computer aided drafting (CAD)

Package name	Supplier
AutoCad, Release 9	Autodesk
Design CAD	American Small Business Co
Auto Sketch	Autodesk
Turbo CAD	Pink Software
In *a* Vision	Micrografx
GenericCADD	Generic Software Inc
LaserCad	DSL Inc

Table H6 Computer aided drafting software for PC's

APPENDIX I

THE SYSTEM DESIGN METHODOLOGY

I1. Introduction

Due to the advancement of physical and mathematical sciences formal methods are available in all engineering disciplines for the design of a wide variety of engineering products. Complex industrial, military and health-care systems are of a multi-disciplinary nature, and formal methods (derived from scientific principles) for the design of such multi-disciplinary systems are not well developed. Many systems also involve human beings as part of the system. The formal system design methodology presented here caters for such human-component systems.

In order to be able to design multi-disciplinary systems, generic abstractions of system properties from the various disciplines are necessary. These abstractions are described in Section 2 and the system-design process in Section 3.

I2. The System and its environment

I2.1 What is a system?

Some 24 definitions of systems have been published in the literature. However, for the purpose of this work a system is defined as an entity which is self-contained on a specific level or sets of levels of abstraction and which transforms a set of input entities to a set of output entities.

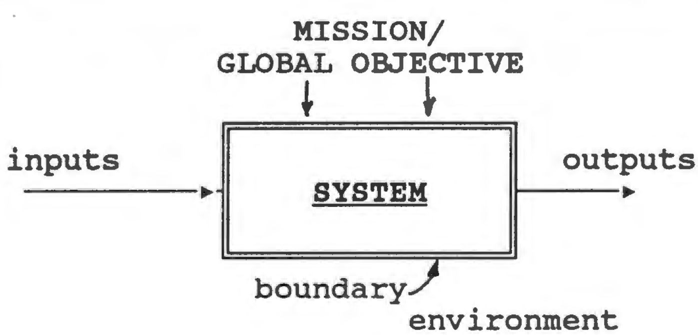


Figure I1 A general system.

I2.2 The boundary of a system

The boundary of a system is that interface which separates the system from its environment. The set of input and output entities flow across this boundary. The boundary of a system is arbitrarily chosen by the system designer in accordance with his design objective.

I2.3 Traits and attributes of systems

A prerequisite to formalised system design is a good understanding of systems in general and the formulation of a set of necessary and sufficient (in order to ensure completeness) traits and attributes of systems. In section I2.3.4 a set of necessary and sufficient system traits as originally developed by Klir (Klir 1969) and as adapted by Gertenbach (Gertenbach 1986), is discussed.

A simplistic view of complex multi-disciplinary systems is seldom possible. The solution can be found in multi-level systems theory (Mesarovic 1970) where various concepts of hierarchies can be employed to formalise the design process. The utilisation of these concepts implies that in addition to the set of system traits, as discussed in Section I2.3.4, some further systems attributes are discussed in the rest of Section I2.3.

I2.3.1 Levels of abstraction

The first system attribute of importance is the level of abstraction from which the system is viewed. Abstraction is a conceptual process where a specific aspect of a system is abstracted from the rest of the system for independent design or analysis within a specific design or analysis context. Multiple abstractions of the same system may be necessary for a complete understanding of the total system. These abstractions must be ordered in some manner. The relation between levels of abstraction is the abstract means by which an entity on a higher level represents an entity on a lower level or how the functioning of an entity on a higher level is realised by one or more functions on a lower level. On higher levels of abstraction the system is viewed in terms of a context, which has the highest possible semantic content to suit the observer, whereas on the lower levels of abstraction a more precise explanation is given of how the system functions.

Abstraction is thus a form of decompositioning which is useful to partition and assign system design-problems to the applicable disciplines or sub-disciplines of science and engineering.

I2.3.2 Levels of functionality

The second system attribute of importance is the level of decision making or functionality which is assigned to the system and its components. A global objective or goal must be assigned to all systems. This goal is associated with the result the system has to produce by the execution of all its functions. In order to increase the level of understanding of this goal, the system should be decomposed into functional units or decision units where every functional unit has to work co-operatively towards a set of sub-goals, the attainment of which will ensure the attainment of the global objective. These functional units should be ordered in a hierarchy of decision-making levels or functionality where higher level units co-ordinate the actions of lower level units and where lower level units present the results of their functioning to higher level units. The relation between levels of decision-making or functionality is thus more tangible than in the case of levels of abstraction. This relation constitutes the objects (inputs and outputs of functional units) which are channelled between levels during their operation.

I2.3.3 Levels of implementation

The third system attribute of importance is the levels of implementation of technology which are employed in the construction of the system. The concept of "levels of implementation" is used to abstract the technological aspects of a system from its structural aspects.

I2.3.4 The set of necessary and sufficient traits of systems

The set of necessary and sufficient traits by means of which a system can be described, is partitioned into two subsets.

(a) Traits related to what work the system does

These traits are:

(1) The function of a system; and

(2) The activity of a system.

The function of a system is that system trait which relates a set of input objects with a set of output objects in terms of a rule of correspondence between the set of input and the set of output objects. Generally this rule of correspondence is the formulation of the behaviour, processing or operation which is applied to the set of input objects in order to produce the set of output objects. It is important to notice that the syntax of a functional description must contain the names of input objects, output objects as well as the name, description or formulation of the rule of correspondence. There are two types of system functions. The first type is referred to as line functions and they are those functions which are directly associated with the processing or conversion of input objects to output objects. The second type is referred to as management functions. They are those functions which are not directly associated with the above processing but they are necessary in order to ensure that the above processing is co-ordinated and the desired results are obtained.

The activity of a system is that trait of a system which describes the set of actions which has to take place within a system in order to ensure that the system executes its functions. All system functions must be analysed in terms of which activities are necessary for the specific function to be realised. This entails a top-down approach to system design where activities eventually, when their related input and output objects are added, become sub-functions of the system on a lower level.

(b) Traits related to the organisation or structure of the system or how work is done within the system

The system traits which are listed above, do not enforce any specific system organisation or structure. In fact nothing about the internal organisation (how work is divided between elements of the system) is enforced by the specification of these traits. In order to formulate the latter, two further system traits, one which models the static and the other the dynamic part of the system organisation, are required. These are:

(1) The structure of elements (from which the system is constructed) and couplings between these elements (EC-structure).

(2) The state transition structure or program of the system (ST-structure).

The EC-structure of a system represents the elements and the interconnectivity between the elements of a system in graphical format. One or more functions (together with their associated activities) of the system are mapped into every system element. It is important to note the difference between the notion of a system function and a system element. System elements are physical parts of the system whereas the function of a system is associated with the behaviour of the system. Functions are mapped into elements; this is the essence of the system design-process as described in Section I3. Together with the above mapping, the input and output objects associated with functions are mapped into couplings between system elements.

There are two types of system elements viz. firstly, processing elements, which process objects such as data, information, materials and energy; and secondly, storage elements, which perform intermediate storage of objects.

Similarly system couplings are also of two types viz. firstly, couplings which represent the flow of objects such as data/ information/ materials/energy or generally those objects which are related to the line functions of a system and secondly, couplings which represent the flow of control or co-ordination. These latter objects are related to the management functions of the system. It is useful to indicate storage elements and the flow of objects associated with line functions with double lines and the other types of elements and couplings with single lines (see Figure I2c).

The ST-structure of a system is a representation of how the dynamics of systems are organised. The state of a system is a condition or mode of operation which the system assumes for a specific (in deterministic systems) time duration. One or more functions (together with their associated activities) of the system are mapped into a specific system state. As a result of some trigger which may be an external event or some internal condition (for example function completion), a state transition will occur and the system will assume a new state. In the new state a new set or combination of functions will be executed. The ST-structure of a system is a graphic presentation of the set of states (see figure I2d) which the system can assume together with the set of transitions between these states.

I2.3.5 System requirements

In the previous section the set of necessary and sufficient system traits was described in terms of what the system must do (functions and activities) and how the system is structured (EC-structure and ST-structure). Associated with these system traits, some other requirements to which the system must comply are identified during the systems engineering process. These requirements are seen as attributes of the set of system traits and during the systems-engineering process they must be allocated to the set of system traits. For example:

(a) range, resolution and level requirements must be allocated as specifications on input/output objects;

(b) reliability, availability, stability or other performance specifications must be allocated as specifications on the rule of correspondence of a function;

(c) modularity and physical requirements of elements (mass, colour, etc.) must be allocated as specifications on the EC-structure;

(d) time limits for function execution or specific requirements on sequential operations must be allocated as specifications on the ST-structure.

I2.4 Summary of System Aspects

The set of necessary and sufficient system traits specifies firstly, what the system must do (functions and activities) and secondly, how the system is organised (EC- and ST-structure).

System requirements are allocated to system traits as attribute specifications. In complex systems a further set of attributes has been identified. This set contains the level of abstraction at which the system or its elements will operate, the level of functionality or decision-making of elements and the level of implementation selected for the implementation of elements.

I3. The system design process

I3.1 Simple systems

The "system-design process" for a simplified situation is summarised in graphical format in Figure I2. The first phase of the design process is the formalisation of what the system must do as shown in Figure I2(a) and it comprises the following:

(1) Determine the boundary of the system.

(2) Identify and formulate in the correct syntax the global system objective and the top level system functions which are generally "visible" across the boundary of the system.

(3) Analyse each system function in terms of its associated set of activities.

In the second phase the actual design of the system is done as shown in Figure I2(b); it comprises the following:

(1) An EC-structure (Figure I2(c)) is created by the mapping of system functions (rule of correspondence and input/output objects) and activities into suitably interconnected elements and couplings.

(2) An ST-structure (Figure I2(d)) is created by the mapping of system functions and activities into a set of system states which are suitably interconnected with state transitions so that the dynamic operation of the system can be realised.

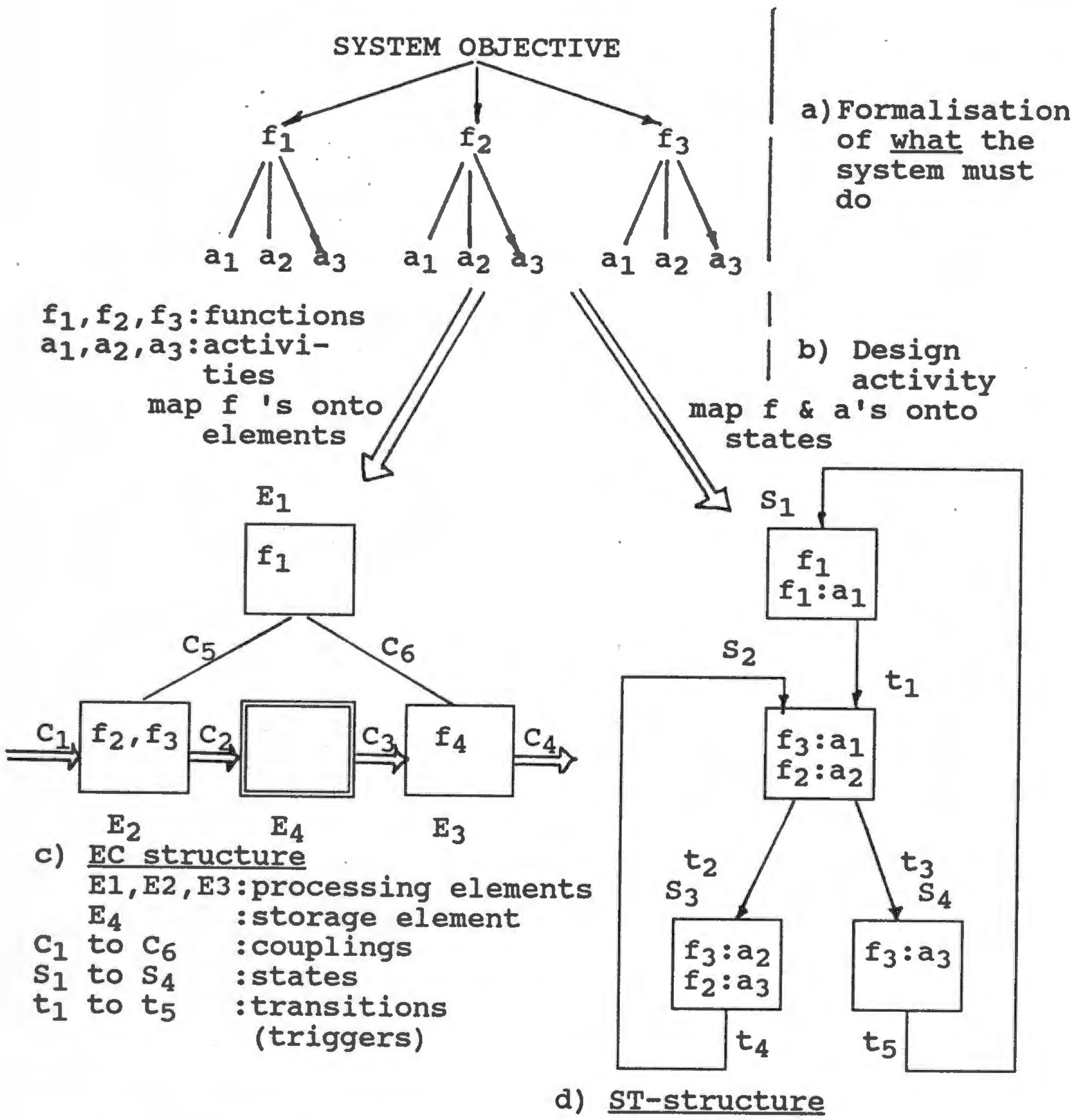


Figure I2 The systems engineering process and resulting structures

The third phase comprises an iteration of the above process. Usually during the second step of phase 2, additional functions which the system should perform are identified and this necessitates a repetition of phases 1 and 2. In fact the second step of phase 2 can also be used as a starting point for system design, since it is ideally suitable for the identification of system functions.

The fourth phase involves the allocation of accumulated system requirements as discussed in Section I2.3.5, to the various system traits.

I3.2 Complex systems

The outputs of the above mentioned design process are EC- and ST-structures with identified elements and states. In the case of complex or multi-disciplinary systems these elements may however again be complex subsystems. The same design process as described above should be repeated for every one of these elements on a lower design level as shown in Figure I2.

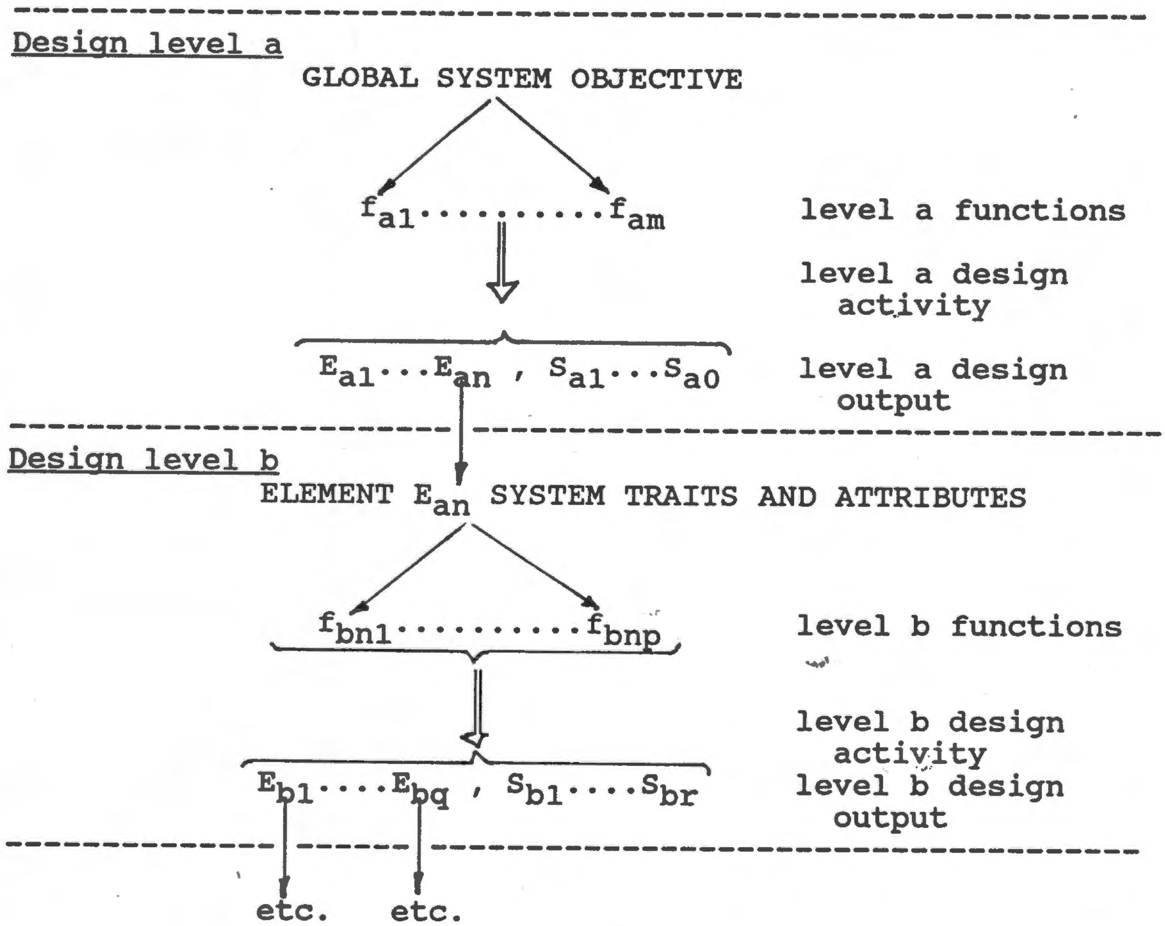
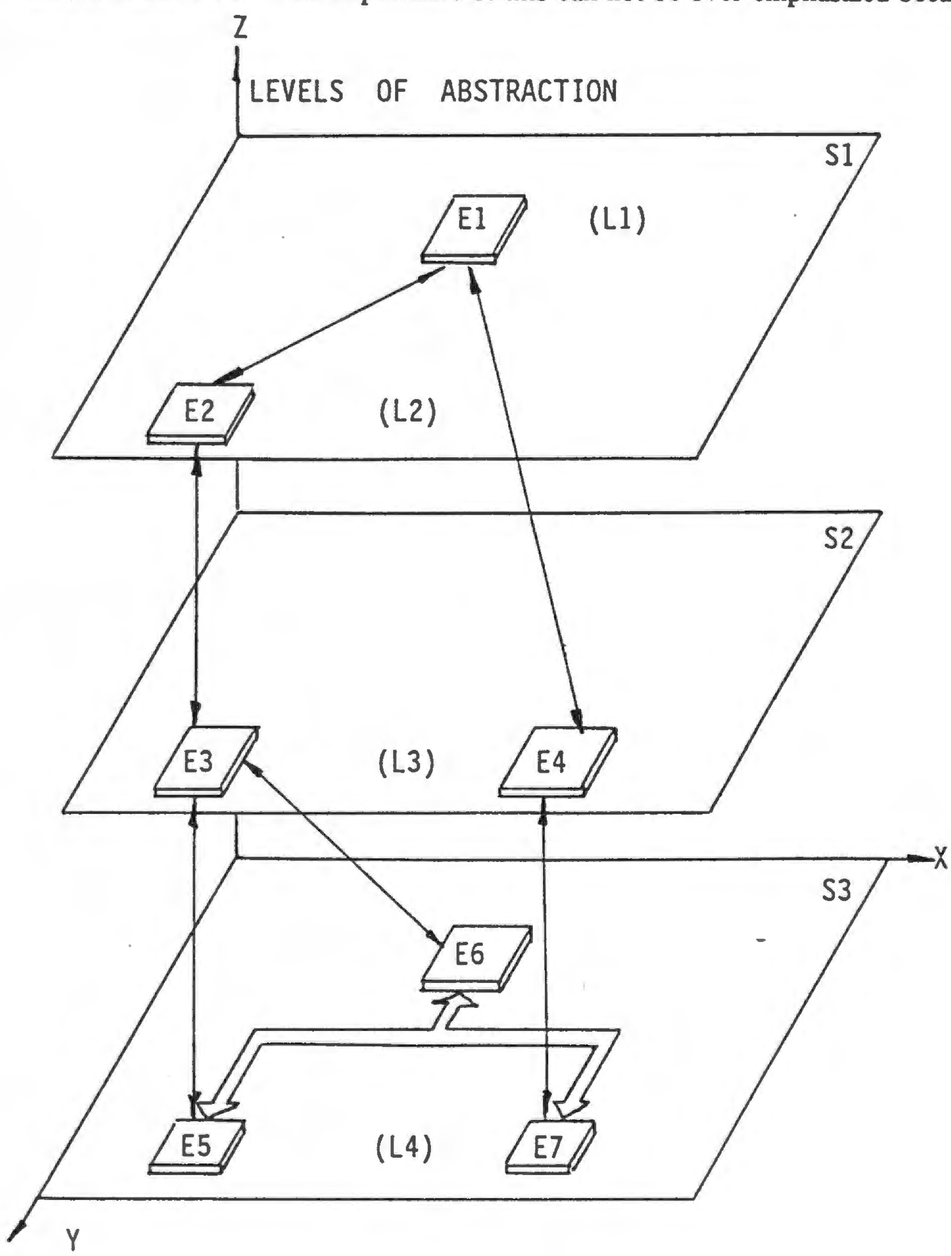


Figure I3 Multiple design levels for complex systems

It is, however, important to note that the starting point for the lower level design is the system traits and att of the system element as identified on the upper design level. Thus the lower level design is given a well-d starting point due to the fact that a functional analyses in terms of activities was made on the upper level. T activities of the upper level can now be simply elaborated upon (viz. add input/output objects) to become fu on the lower level. The importance of this can not be over-emphasized because this is the mechanism by m



E1 to E7 : system elements
S1 to S2 : levels of abstraction with abstracted EC-structure
L1 to L4 : levels of functionality

Figure I4 Three dimensional EC-structure for complex systems which the interfaces between elements on the upper level are controlled and compliance with the upper level system objective is maintained. Thus, the designer on the lower level may not add functions or activities which can not be logically derived from upper level activities or which change the interface to other elements. Strict interface control makes it possible to decouple design efforts on lower levels. This is absolutely essential in complex systems, especially of a multi-disciplinary nature such as health-care.

In the case of a complex system, a simple two dimensional EC-structure is not sufficient for the complete description of the structure of such a system. The hierarchical concepts of Section I2.3 are the only other structural attributes of systems. Thus, they should be used as aids for the structural design of complex systems. This will, however, call for three-dimensional EC-structures. This is shown in Figure I4.

In this figure the lower x,y plane is called the topology plane and on it a global system EC-structure (E5 to E7) which forms a framework for all system elements, is designed (for example the topology of a distributed process control system). Along the vertical axis various abstractions of the system (S1 to S3) are made (see Section I2.3.1). Superimposed on these levels of abstraction is shown a hierarchy of functional levels (L1 to L4) (see Section I2.3.2) which also contain the same system elements E1 to E7.

APPENDIX J

THE SYNTHESIS OF THE ICE MODEL

J1 Introduction

The ICE model is a complex multi-disciplinary system. The synthesis is consequently also complex and it is easy to lose track during the synthesis process. The synthesis process is executed in several levels and abstractions. However a common theme is encountered throughout, namely the decompositioning of function into activities, inputs and outputs, EC diagrams and ST diagrams. The outline in which this function decompositioning will be presented in the synthesis is summarised below:

1 Objective of the system

2 Environment of the system

3 List of system functions ($f_a...f_n$)

4 Description of functions

4.1 Function f_a
- * description
- * list of activities
- * list of inputs
- * list of outputs

4.2 Function f_b

. . . .

. . . .

4.n Function f_n
- * description
- * list of activities
- * list of inputs
- * list of outputs

5 System organisation

5.1 EC-structure
- * mapping of functions and activities to system elements and
- * inputs and outputs to couplings

5.2 ST-structure

Figure J1 The outline of the synthesis process

As was discussed in Appendix I, complex systems are designed in a top down approach in as many design levels as are necessary for complete system understanding (figure I3). The first level , or <u>level A</u>, is given below.

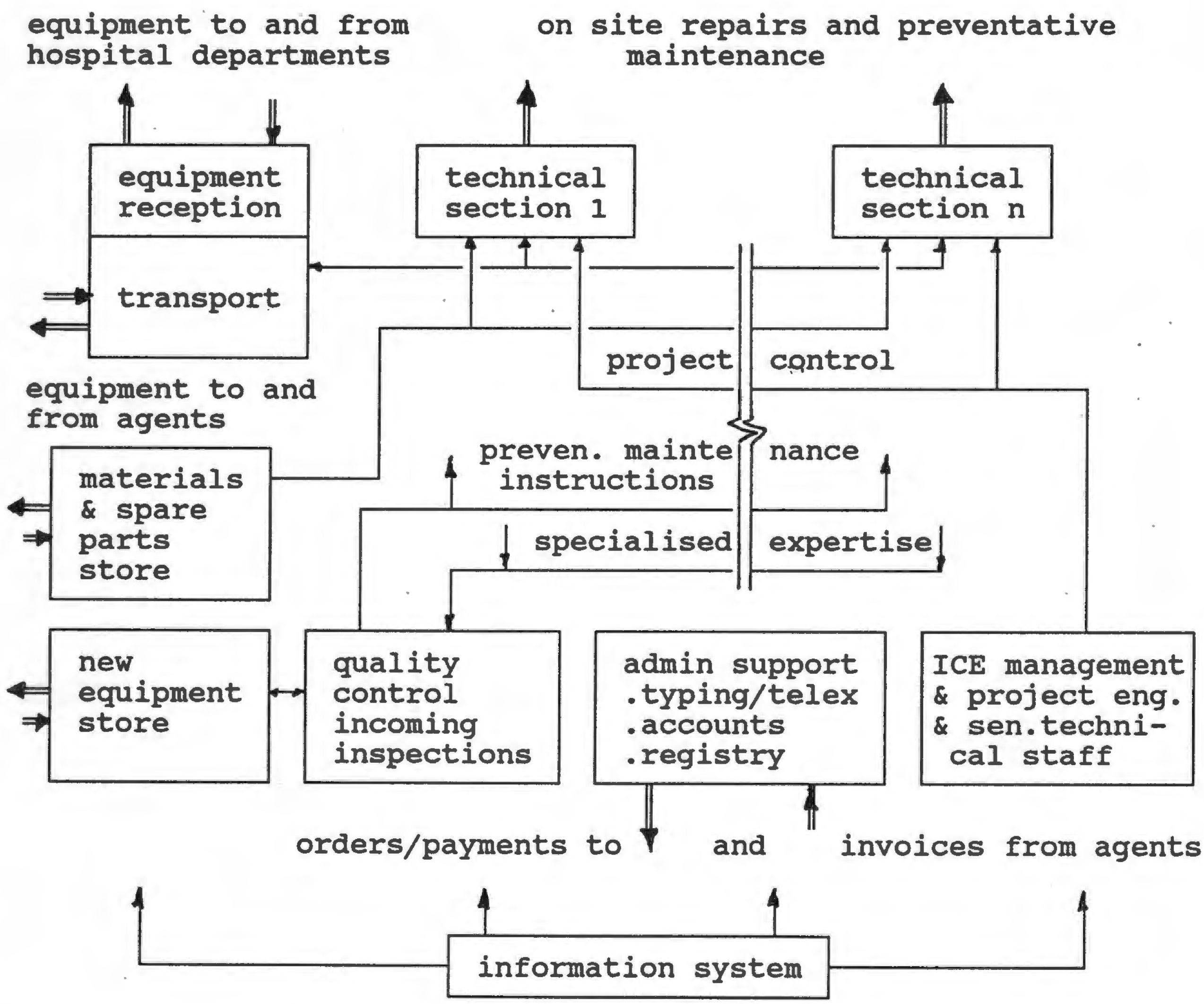


Figure J2 <u>The ICE department</u>

J2 <u>The objective of the ICE model</u>

The objective of the ICE model is to provide (global activity) technology support (output) in a cost-effective and safe manner (standard).

J3 The environment of the ICE model

The ICE model is a system that functions within the organisational framework of a typical hospital clinical engineering department. (See figure J2).

The computer-based part of the information system is shown in figure J3 below.

This department is one component of the larger more complex health-care technology system

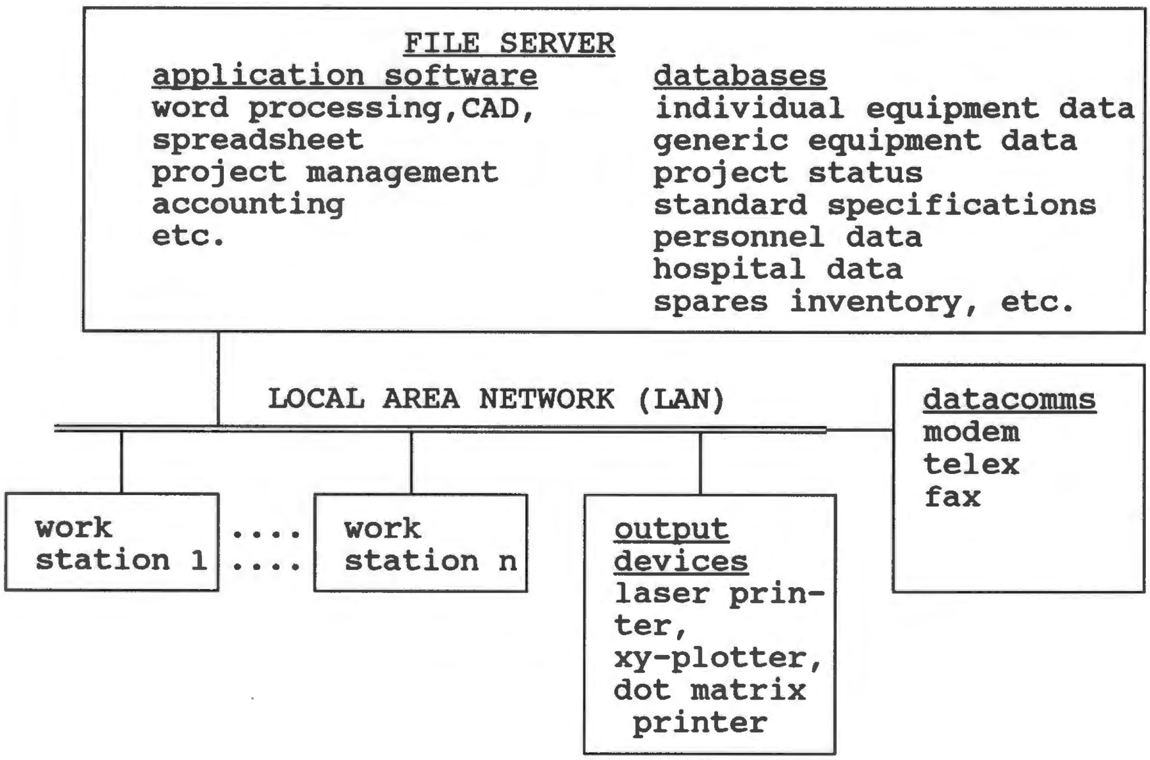


Figure J3 The decision support system hardware

shown below in figure J4.

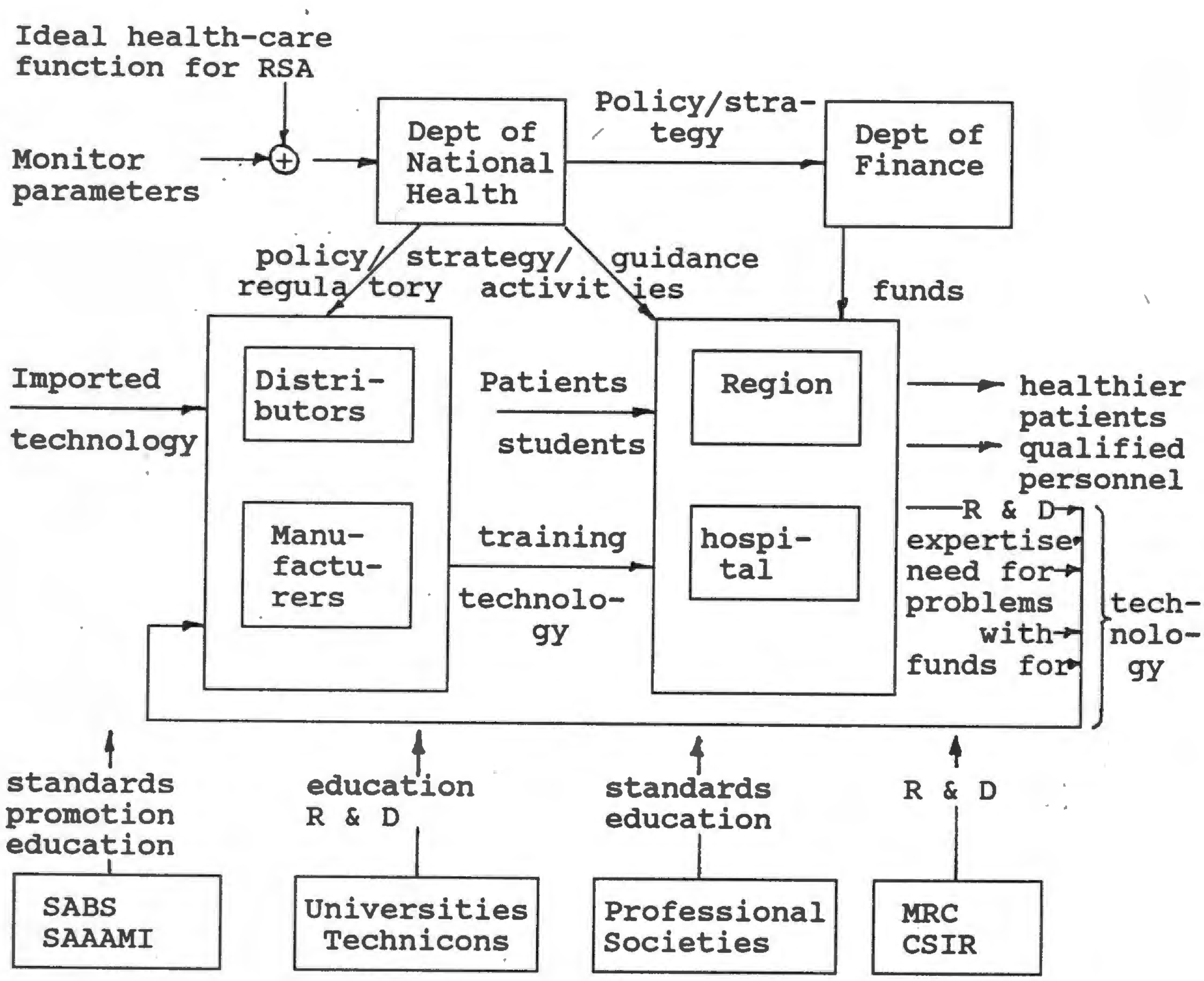


Figure J4 The health-care technology system

To enable the analysis of such a complex system, the health-care technology system is partitioned both vertically and horizontally as follows:

	patient care	technology	finance	education
national level		vertical partitioning		
regional level				
hospital level		The ICE model		
home level			horizontal partitioning	

Figure J5 A partitioning of the health-care technology system

J4. List of functions of the ICE model

description	standard
provide technology support	see note below

Note: The standard column will normally contain reference to procedure manuals that describe how each specific function is to be executed. These procedures manuals will by definition be specific to the organisation for which the system is designed.

J5. Description of functions

J5.1 The technology support function

(a) Description

To provide technology support from the given resources in a cost-effective and safe manner

(b) List of activities

description	standard
Technology planning Acquisition(of technology) Commissioning Support Replacement Education Management Maintain database Administration Decision support	

(c) List of inputs

description	standard
Resources (money, materials, manpower) Students Hospital performance indicators Decision support information Technology support request	

(d) List of outputs

description	standard
Technology support Trained personnel Research & development Decision support information	

J6. System organisation

J6.1 The EC-structure of the ICE model

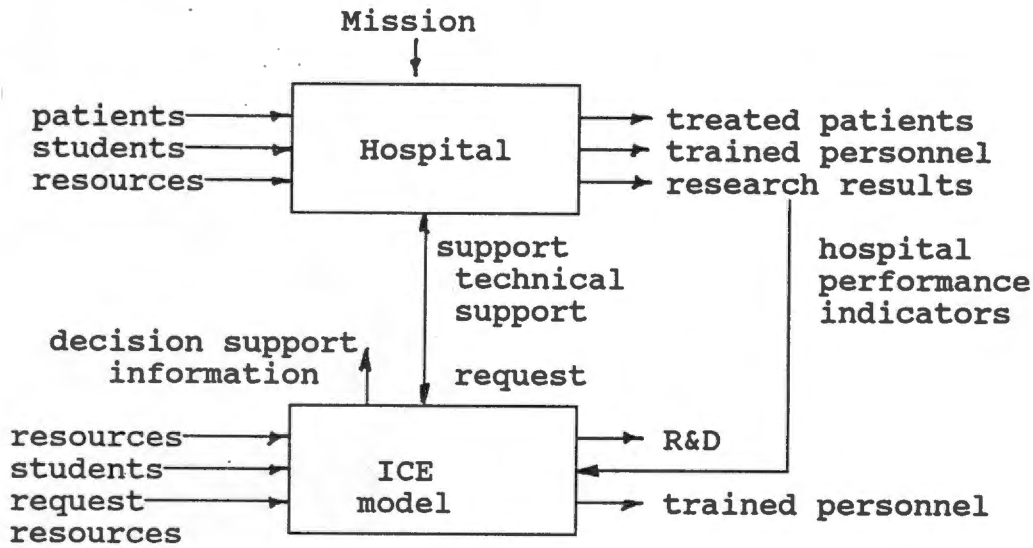


Figure J7 The clinical engineering system in the hospital environment

J6.2 The ST-structure of the ICE model

The functions (at this design level there is only one global function) and activities are mapped onto the global state transition structure. For clarity only the major points are shown in the ST-structure in figure J8 below.

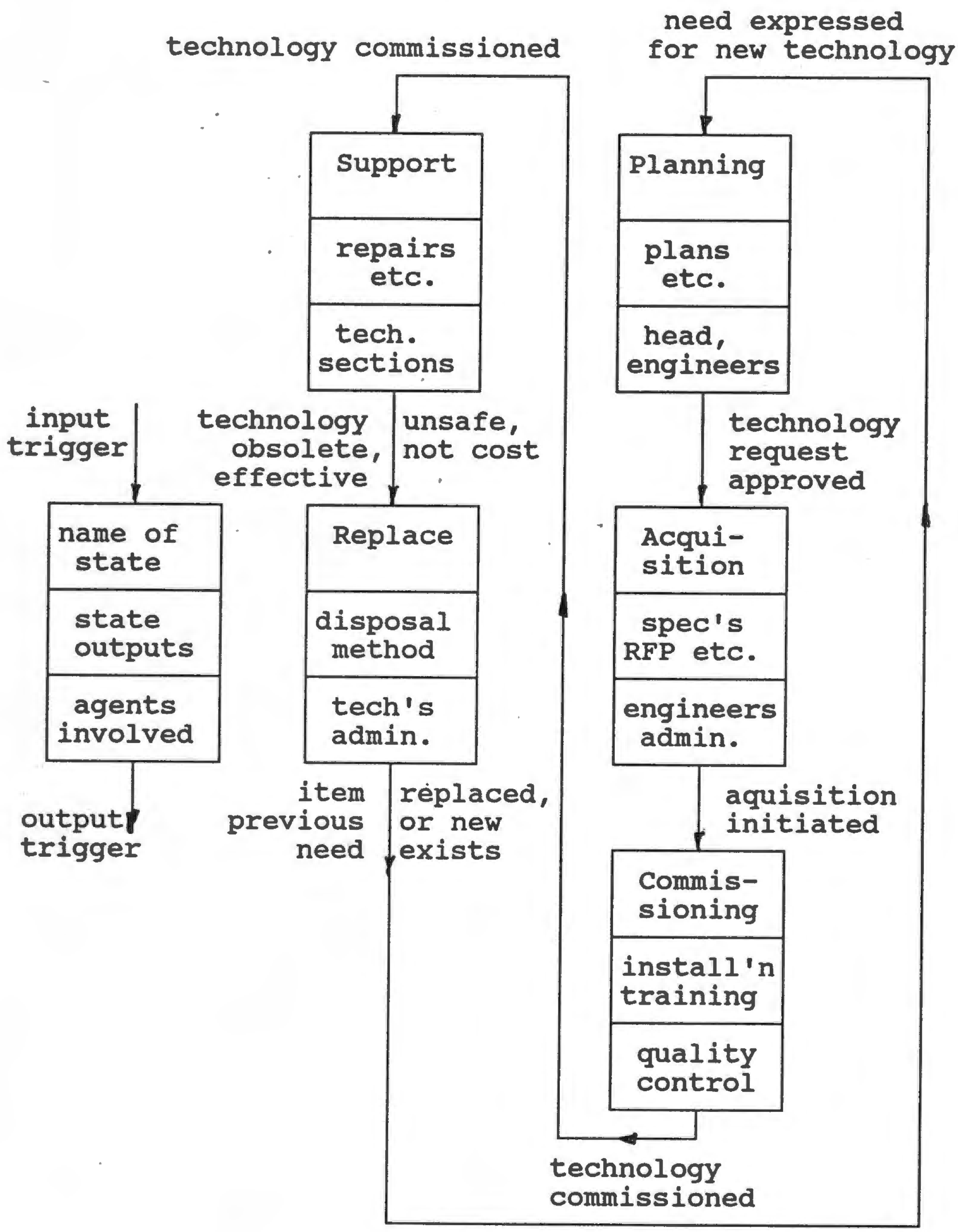


Figure J8 <u>The ST-structure of the ICE model</u>

For further synthesis, the activities of the ICE model become functions of the next system design level. These new functions are grouped together in three sub-systems that are dealt with in three different abstractions:

- the general management system
- the ICE support system
- the decision support system

These are shown in figure J9.

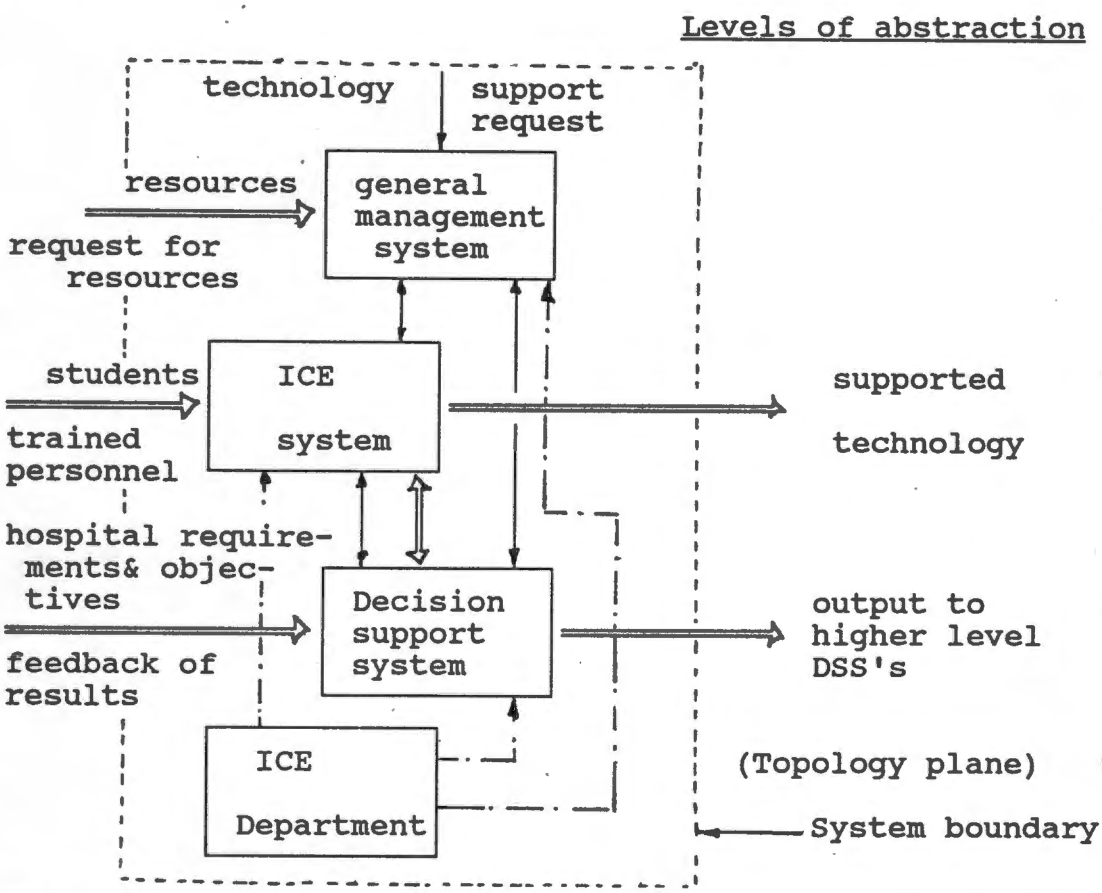


Figure J9 Levels of ICE model abstractions

Further decomposition of the ICE model followed the same pattern until it was synthesised to sufficient detail to permit the definition of the ICE decision support system (see figure J10).

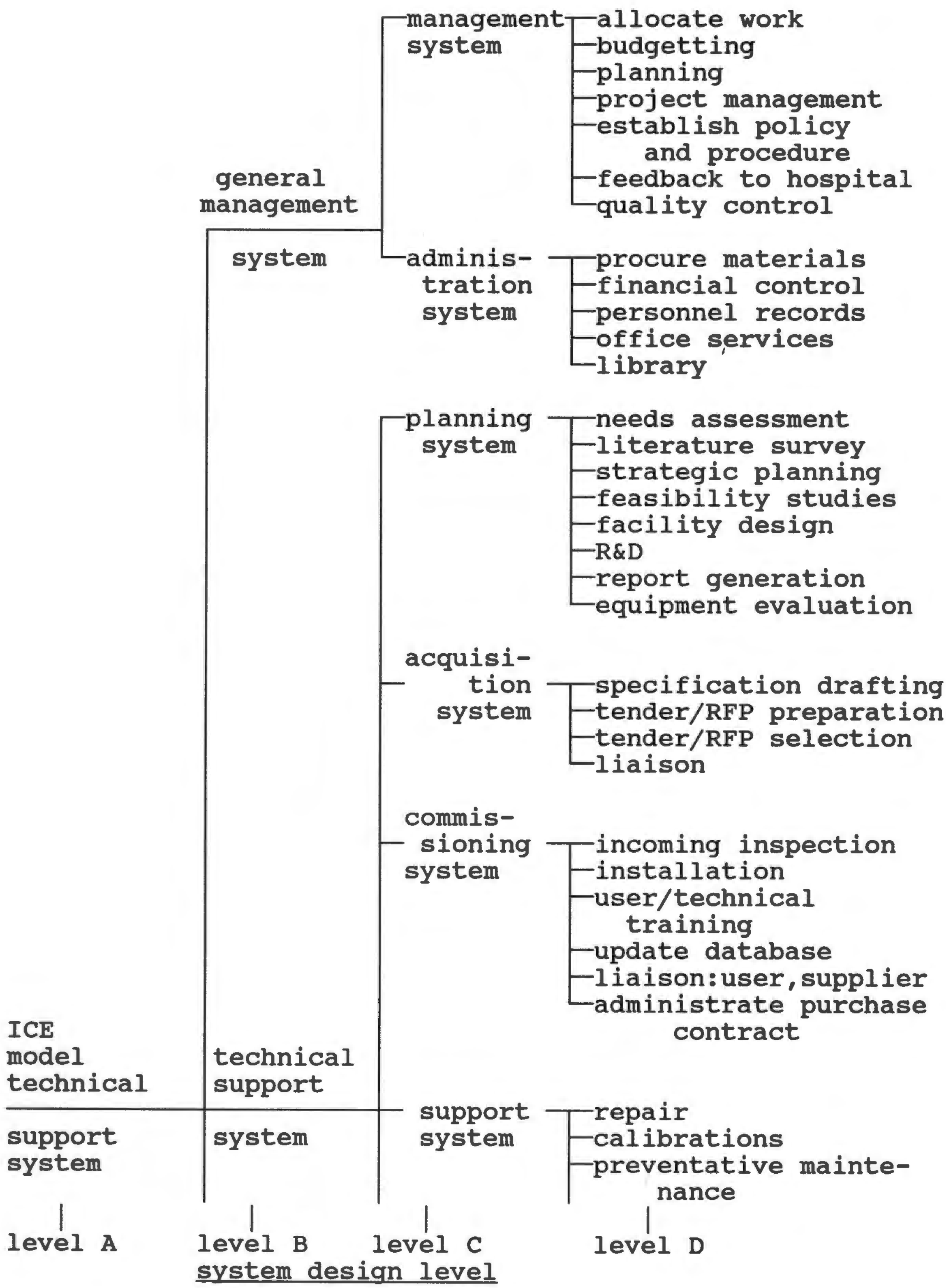


Figure J10(a) ICE systems design tree

- support system
  - system
    - support system
      - repair
      - calibrations
      - preventative maintenance
      - performance & safety testing
      - manufacturing
      - modifications
      - service contract administration
      - hazard recalls
      - update database
      - feedback:user, management
    - replacement system
      - cost, history analysis
      - equipment condition inspection
      - disposal recommendation
      - salvage components
      - update database
    - education system
      - plan/prepare courses
      - run courses
      - monitor progress
      - liaison with education institutions
      - keep records
  - decision support system
    - maintain database system
      - collect ICE information
      - collect external information
      - process information to proper format
      - send information out
      - security/back-up
    - decision making system
      - interpret hospital policies
      - generate strategies/ alternatives
      - monitor feedback from actions
      - presentation of results

level A | level B | level C | level D

system design level

Figure J10(b) ICE systems design tree(continued)

APPENDIX K

CLINICAL ENGINEERING AND BIOMEDICAL ENGINEERING DEFINITIONS

(from the ICC with permission)

INTERNATIONAL CERTIFICATION COMMISSION
1901 N. Ft. Myer Drive, Suite 602
Arlington, Virginia 22209
703-525-4890

GENERAL INFORMATION

The International Certification Commission, whose membership provides a broad representation of relevant members of the health-care community, including representatives from engineering, medical, industrial, and governmental groups and agencies, supervises the certification of clinical engineers, biomedical equipment technicians and other related specialists through the organization of examining boards.

Guided by the Commission, the Board of Examiners for Clinical Engineering Certification considers a clinical engineer to be an engineer whose professional focus is on patient medical device interfacing, one who applies engineering principles in managing systems and devices in the patient setting.

The clinical engineer's level of education, experience and competence enables him or her to participate professionally with physicians, hospitals administrators and other personnel in the technological aspects of health-care delivery. The clinical engineer has intensive knowledge in at least one branch of engineering adequate to qualify as a professional engineer. Knowledge of regulations, codes and administrative problems is adequate for a supportive role in hospital administration. The clinical engineer's teaching ability is suitable for involvement in in-service education of equipment users. Finally, the clinical engineer has the professional maturity required to understand ethical conduct and to work in the best interest of the patient and general public.

To differentiate between clinical engineers, biomedical equipment technicians, and biomedical engineers, the Board considered a biomedical equipment technician to be a technician whose professional focus is on the repair and maintenance of medical devices or research devices as used in applied or basic care research.

The biomedical equipment technician installs, inspects, repairs, calibrates and modifies medical devices, health-care research devices and medical support systems; advises concerning theory of operation, underlying physiological principles and safe clinical application of medical devices; and supervises biomedical equipment maintenance activities.

The Board considers a biomedical engineer to be an engineer whose professional focus is on the design and development of medical devices; one who utilizes engineering principles and methods in the solution of problems in biology and medicine. The biomedical engineer usually works in a corporate or university research setting applying the principles and methods of engineering to the design and development of devices used in conjunction with living organisms. In biological research, the biomedical engineer applies an engineering approach which is relevant and productive to both biological and engineering science. Utilizing knowledge of both sciences, the biomedical engineer works on the development of basic theory.

APPENDIX L POTENTIAL FOR SHARED CLINICAL ENGINEERING SERVICES

In tables L1 to L3 a list of postal codes is given where two or more hospitals are located at the same postal code. Such hospitals are theoretically in close proximity and could be potential candidates for shared clinical engineering services.

postal code	no. of hospitals	total no. of beds	average	min.	max.
0001	8	4787	598	39	1720
0002	2	205	103	45	160
0083	4	331	83	36	162
0132	4	641	214	30	192
0300	3	641	214	30	324
0400	6	2228	371	18	501
0480	2	144	72	67	77
0600	2	366	183	94	272
0700	4	2000	500	36	1240
0850	2	216	108	46	170
0900	2	118	59	29	89
1000	2	273	137	43	230
1035	3	595	198	108	355
1120	2	193	97	44	149
1160	2	146	73	73	73
1300	3	568	189	11	317
1400	2	300	150	80	220
1413	3	965	322	170	575
1460	3	791	264	26	709
1500	4	1170	293	48	550
1540	2	432	216	46	386
1560	4	846	212	38	667
1573	2	111	56	11	100
1610	3	911	304	180	550
1620	3	91	30	15	60
1645	2	199	100	79	120
1700	2	204	102	66	138
1710	3	348	116	8	203
1740	6	2009	335	3	788
1760	7	5451	779	90	2885
1900	3	307	102	18	232
1930	4	1465	366	24	1294
2000	9	1921	213	23	1075
2006	2	930	465	180	750
2013	3	3600	1200	430	2740
2018	4	793	198	84	405
2021	2	485	243	204	281

Table L1 Areas potentially suited to shared CE services

postal code	n^o of hospitals	total n^o of beds	average	min.	max.
038	4	805	201	121	298
2044	2	1023	512	242	781
2092	2	108	54	18	90
2094	2	68	34	29	39
2125	2	282	141	141	141
2130	3	393	131	25	273
2210	2	72	36	35	37
2235	2	81	41	40	41
2250	2	60	30	30	30
2280	5	496	99	32	304
2350	3	337	112	18	253
2380	2	296	148	62	234
2400	2	144	72	24	120
2430	2	337	169	120	217
2500	2	670	335	40	530
2520	2	1956	978	2996	1660
2570	3	1059	353	36	965
2940	3	2156	719	52	1818
2980	3	155	52	24	101
3100	3	505	169	48	370
3145	2	42	21	12	30
3200	5	3736	747	404	1645
3201	2	8	4	4	4
3290	2	699	350	5	624
3310	2	289	145	21	268
3370	2	648	324	28	620
3550	3	272	91	19	128
3660	2	496	248	238	258
3780	2	557	278	7	550
3765	3	515	172	96	264
3880	2	992	496	122	870
4000	6	1649	275	30	880
4030	2	930	465	236	694
4060	2	1518	759	120	1398
4220	2	520	260	260	260
4240	3	871	290	144	410
4341	2	63	32	20	43
4453	2	130	65	60	70
4730	2	510	255	250	260

Table L2 Areas potentially suited to shared CE services

12 MAR 1990

postal code	n^{o} of hospitals	total n^{o} of beds	average	min.	max.
4900	27	5783	214	24	803
5200	2	1092	546	148	944
5201	2	78	39	14	64
5208	2	1000	500	300	700
5320	3	1229	410	26	891
5530	2	188	94	93	95
5720	4	924	231	10	661
6000	4	575	144	12	357
6001	2	152	76	10	142
6055	2	620	310	300	320
6120	2	736	368	36	700
6140	3	871	290	104	475
6230	2	620	310	210	410
6280	2	241	121	120	121
6530	5	557	111	8	237
6850	2	697	349	287	410
7200	2	68	34	33	35
7300	2	191	96	50	141
7450	2	998	499	101	897
7460	2	236	118	60	176
7530	4	1150	288	35	890
7620	2	384	192	66	318
7700	5	427	85	14	282
7735	2	124	62	41	83
7800	7	1074	153	46	320
7925	2	1828	914	28	1800
8000	4	191	48	13	73
8001	7	394	56	6	124
8300	5	1742	348	58	687
8446	2	55	28	2	53
8460	2	333	167	66	267
8670	2	1336	668	72	1264
9000	81	8062	100	2	1310
9300	5	3306	661	90	1127
9301	2	40	20	20	20
9460	4	1348	337	27	850
9490	2	477	239	127	350
9570	3	199	66	19	146
9700	2	328	164	136	192
9785	2	1402	701	400	1002

Table L3 Areas potentially suited to shared CE services

(note: postal code 9000 represents the whole of South West Africa)