STANDARDS FOR BIOMEDICAL DEVICES IN FOREIGN COUNTRIES AND TURKEY

by

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FOREIGN COUNTRIES AND TURKEY

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ABSTRACT

In this study, the standards and the standardizing organizations of biomedical devices which are very important in health-care are investigated.

The regulations of biomedical devices in U.S.A , Canada and Europe countries are described briefly.

In Turkey, T.S.E (The Turkish Standards Institute) which is the only organization in standardization is described. The topics for Health Preparatory Group in 1985-1986 of T.S.E and the relevant standards until 1984 are investigated. The biomedical devices and the hospital equipment manufacturers are investigated. T.S.E Standards related to medical devices are given in Tables.

Finally,testing procedure on medical devices produced in Turkey and for imported ones are recommended.

ÖZETÇE

Bu çalışmada, insan sağlığı için çok önemli olan biyomedikal cihazların standardları ve standard hazırlayan kuruluşlar incelenmiştir.

Amerika, Kanada ve Avrupa ülkelerindeki biyomedikal cihaz standard çalışmaları kısaca anlatılmıştır.

Türkiye'de standardlar alanında tek kuruluş, olan T.S.E'nin tanıtımı ve sağlık grubunun 1984'e dek yaptığı çalışmalar ve 1985-1986 programı incelenmiştir. Türkiye-de üretilen tüm hastane donanımı, tıp cihazları ve üreten firmalar araştırılmıştır. Bunlardan hangilerinin standardı olduğu tablolar ile verilmiştir.

En son olarak da Türkiye'de üretilen ve ithal edilen tıp cihazları için test yöntemleri önerilmiştir.

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I. THE STANDARDIZATION

Standardization is one of the most fundamental tools in economic and industrial development.

The stated purpose of the ISO for standardization is to "facilitate international exchange of goods and services and to develop mutual cooperation in intellectual, scientific, technological, and economic ability."

ISO defines standardization as : "The process of formulating and applying rules for an orderly approach to a specific activity for the benefit and with the co-operation of all concerned and in particular for the promotion of optimum overall economy taking due account of functional conditions and safety requirements".

Codes : In the technological environment, a code is usually defined a system of principles and regulations or a systematized body of law. Thus, codes represent the accumulation of a system of regulations which usually are enforced under an active law by a local, state or federal goverment agency. One of the most familiar codes is the

National Electric Code (NEC) which was developed by the National Fire Protection Association (NFPA), is promulgated as an American National Standard under the procedures of the American National Standards Institution (ANSI), and usually is enforced by localities as part of their regulations for the construction or building industries.

Regulations : Regulations are rules normally promulgated by the government and codified in the various codes. These rules or regulations are a method by which the government communicates with the public, industry, and other interested parties.

Specifications : Specifications are documents used to control the procurement of equipment and buildings. In most applications of a general nature usually reference other specifications, standards, handbooks, and drawings. Specifications usually cover design criteria, materials, processes, test methods, technical data, inspection, and other items necessary to procurement by establishing a technical agreement between the procuring activity and the contractor as to what is desired and what quality will be accepted.

A specification may be a standard, a part of a standard or independent of a standard.

1.1 THE AIMS OF STANDARDIZATION:[16]

1. Simplification of the growing variety of products and procedures in human life.
2. A communication between the manufacturer and the customer.
3. Safety, healt and protection of life.
4. Protection of consumer and community interests.
5. The elimination of trade barriers.

1.2. THE PRINCIPLES OF STANDARDIZATION :[16]

(1).Standardization is essentially and act of simplification as a result of the conscious effort of society. It calls for a reduction in the number of same things. It not only results in a reduction of present complexity but aims at the prevention of unnecessary complexity in the future.

(2). It is a social as well as an economic activity and should be promoted by the mutual cooperation of all concerned. The establishment of a standard should be based on a general consensus.

(3). The mere publication of a standard is of little value unless it can be implemented. Impementation may necessitate by the few for the benefit of the many.

(4)_ The action to be taken in establishing standards is essentially one of selection followed by fixing.

(5)_ Standards should be reviewed at regular intervals and revised as necessary. The interval between revisions will depend on the particular circumstances.

(6)_ When performance or other characteristics of a product are specified, the specification must include a description of the methods and tests to be applied in order to determine whether or not a given article complies with the specification.

When sampling is to be adopted the method, and if necessary the size and frequency of the samples, should be specified.

(7)_The necessity for legal enforcement of national standards should be deliberately considered, having regard to the nature of the standard, the level of industrialization and the laws and conditions prevailing in the society for whom the standard has been prepared.

1.3 GROUPS OF STANDARDS [3,10]

Standards may be voluntary or mandatory in their implementation. Also there are some proprietary standards.

1.3.1 Voluntary Standards :

These are developed under consensus process where manufacturers, users, consumers and government come together voluntarily in open public sessions. In the consensus process, the document is made available to all interested parties.

The process of consensus is a means of developing a satandard that is acceptable by groups with widely disparate outlooks and interests. Such a standard is commonly called a voluntary standard, in that it may be voluntarily accepted and adhered to by those involved in its development, as well as other concerned parties.

An example of how one particular organization develops a voluntary standard is described here. This organization is NCCLS (National Committee on Clinical Laboratory Standards) in USA.

In NCCLS, a major effort is put into the initial decision to undertake a project. Included is a rationale prepared by the individual or group making the proposal, a review by chairpersons of existing commitees, a budget review, and finally, a decision by the board of directors. Since NCCLS is made up of representatives from the health profession, industry, and government, this process of justifying a project ensures that all pertinent information has been considered. Figure 1 shows a diagram of the subsequent development process within NCCLS.

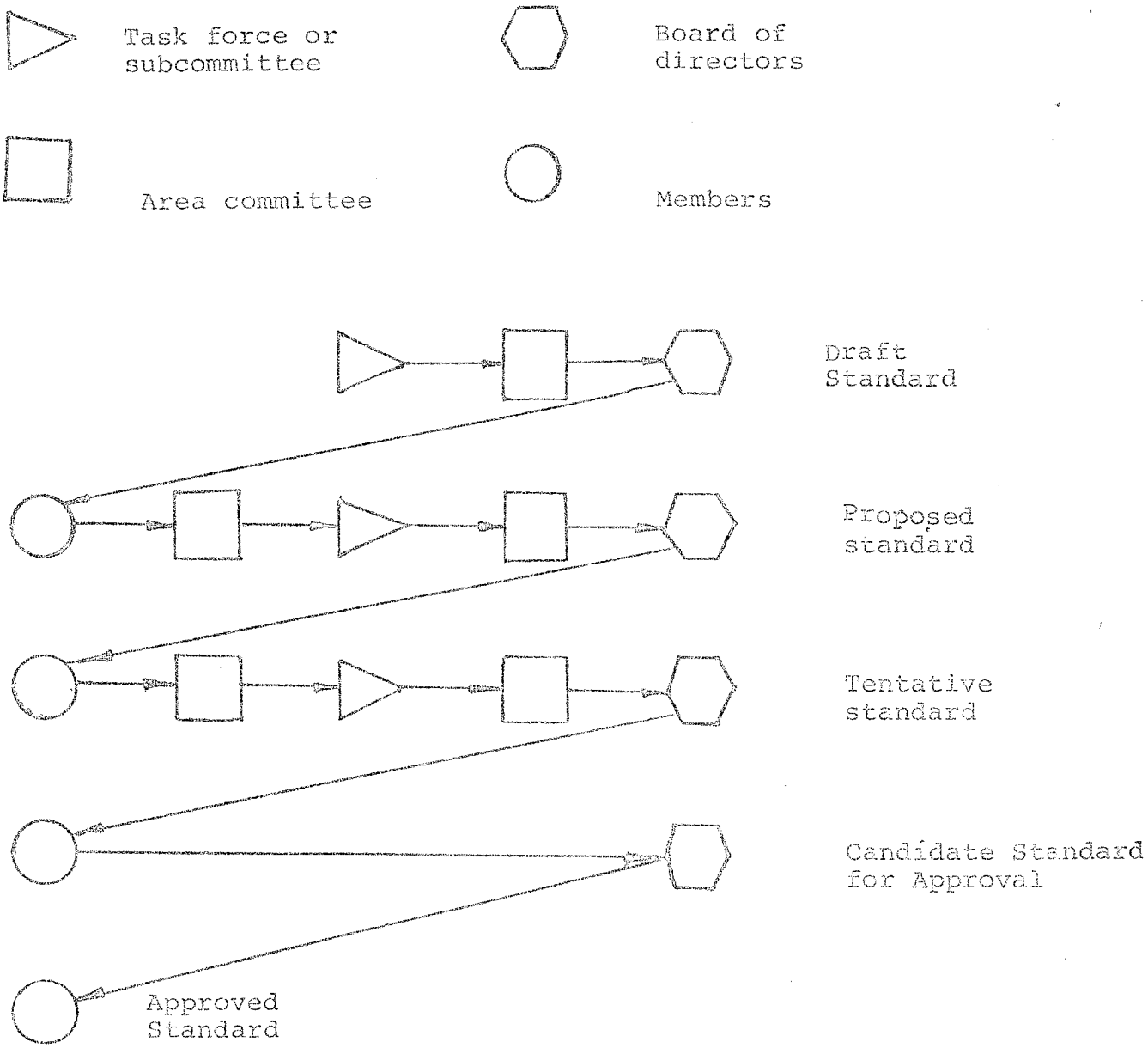

Fig. 1: The National Committee on Clinical Laboratory Standards Consensus Process

As a rule, an approved project is undertaken by a subcommitee or task group made up of experts in that subject matter. They prepare a draft standard that is then presented to the NCCLS committee in whose area of clinical laboratory practice the project falls (the area committee). The area committee reviews the draft and, if acceptable, sends it to the board of directors. Review by the board takes place to decide if the draft standard should be published as a proposed standard. A proposed standard is available to the entire membership and to interested nonmembers for comment. Comments make their way back to the subcommittee, which responds, documents that response, and, by majority decision, prepares a revised document that is sent to the area comittee. The area committee then reevaluates the project. An important consideration at this point is the adequacy of the response to dissenting or negative comments.

If acceptable to a majority of the area committee, the document goes to the board for a decision on publication as a tentative standard. A tentative standard represents a unique step in the consensus process. While tentative, the standard is intended to be used by the NCCLS membership for a period of one year as a practical test of its provisions.

The comments that come back as a result of the provisional use of a standard are sent to the subcommittee and the process of comment, response, revision and approval

begins again. The board of directors then makes a decision on whether to publish it as a candidate standard for approval. This is the final ballot stage, with a 60-day period and a requirement that two-thirds of the members voting approve.

At any stage, decisions can be appealed on procedural or technical grounds. The final decision on appeals within NCCLS rests with the board of directors Additional appeal is available through the American National Standards Institute (ANSI), which has accredited NCCLS as a voluntary standard group.

Approved standards are reviwed every three years. The area committee, alerted by the national office, begins the reviews at about 30 months, leading to a recommendation to the board about what extent of revision, if, any is needed. Depending on the extent of revision, the document will reenter the system either as a candidate for approval, a tentative standard or as a proposed standard. The process then repeats as with a new standard proposal.

The NCCLS system is an excellent example of a carefully thought-out process, replete with safeguards, to establish a voluntary consensus standard.

1.3.2 Mandatory Standards :

The standards which are required by law. It means

that an authority requires adherence to by those over which it has juristiction.

In USA the federal government, under the Radiation Control for Health and Safety Act of 1968 (P.L. 90-602) empowers the Food and Drug Administration (FDA) to develop mandatory product performance standards for several medical devices. Standards for medical devices can also be developed under the authority of the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (P.L. 94-295).

1.3.3 Proprietary Standards :

Probably the smallest percentage of technological standards are those of a proprietary nature. They are developed either by a company for its own internal use or by a trade association for use by its member. In USA some examples of proprietary standards can be found within the Compressed Gas Association. Proprietary standards can serve as a basis for voluntary or mandatory standards if the appropriate exposure is given to these standards and if there is consensus reached among all parties.

1.3.4 International Standards :

International standards promote the free flow of goods by creation of a common economic language among nations. International standards play an important role in helping promote commerce and reducing trade barriers.

The two major international standardization bodies, the International Organization for Standardization (ISO) and the Intenrational Electrotechnical Commission (IEC), have produced more than 2500 standards and the number is expected to double in the next five years. Also there are International Organization for Legal Metrology (OIML), and the International Federation of Clinical Chemists (IFCC).

ISO : The ISO was founded in London in 1946 when 64 delegates representing 25 nations met to consider forming an international standards organization. The object of the proposed organization was "to facilitate the international coordination and unification of industrial standards." At that time about 150.000 national standards were in existence, so the organization's early efforts were concentrated on the coordination of these standards. But, since national standards work had first priority following World War II, only limited interest was expressed in the organization. By the 1960 s, however, international standardization was growing because of the proliferation of multinational corporations whose operations could be hindered by conflicting national standards. Today the national standards bodies of 73 countries (Known as member bodies) are represented in ISO and are working in virtually every area of technology with the exception of electrotechnical matters, the province of IEC.

Appendix 2 gives the medical device commities of ISO.

The USA member body in ISO is ANSI, which holds a voiting membership on 107 of the total 150 ISO technical committees. The Turkish member body in ISO is TSE.

An ISO docement goes through a number of stages before it is accepted as an international standard. After a draft is written by a working group or a subcomittee, it is submitted to the responsible technical committee. Following agreement by the committee, it is sent to the secreteriat for registration as a draft international standard (DIS); the DIS then is circulated to all member bodies for voting. If 75 percent of the votes are cast in favor of the DIS, it is sent to the ISO Council for final acceptance as an international standard.

ISO is financed through member dues and the sale of standards. When ISO publishes a standard, a limited number of free copies are distributed to its members who, in turn, may reproduce and sell the standards. A predetermined amount of the selling price is returned to ISO headquarters.

*IEC : IEC was formed in 1904. The members of the commission are from the national committees, i.e., one for each country represented. Currently, there are 45 such national committees.

*IEC is explained in details in chapter 3

The IEC Technical Committe 62 on Electrical Equipment Used in Medical Practice is the primary comittee concerned with medical equipment. The IEC 62 has four major subcommittees of which the USA has the Secretariat for IEC 62D on medical equipment.

Development of international standards is a slow procedure, measured in years. Drafts are prepared, meetings are held, comments or votes are taken, and revisions are issued in a continuing attempt to resolve differences among national standards of the participating countries. Upon completion of the process, the published international standard may begin to be referenced or adapted as a requirement by regulatory agencies and national standards organizations throughout the world.

1.3.5 The National Standards :

The national standards promulgated after consulting a consensus of all the interests concerned in a country, through a national standards organization which is recognized as the proper authority for the issue of such standards. These standards may be either regulatory or voluntary.

Differences among foreign national standards can create problems for manufacturers attempting to market products internationally.

Significant and unwarranted differences among

foreign national standards may, in some cases, be traced to nonfariff barriers to trade protecting local manufacturers. International standards offer some hope in reducing the differences among foreign national standards.

Appendix 1 : The list of National Standardizing Organizations. Addresses of 91 nations.

II. STANDARDIZATION IN TURKEY AND MEDICAL STANDARDS

2.1 THE TURKISH STANDARDS INSTITUTION (TSE)[1,2] :

Standardization, had been started to be applied in Turkey in a conscientious manner towards the ends of the XV. and the beginning of the XVI. centuries.

In the above-mentioned years, during which the Ottoman Empire enjoyed its most powerful and prosperous period the administratiors of the state incorporated primarily an orderly domestic economy based on standards. This approach formed the basis of the political and military successes atained against foreign countries. As a matter of fact, the document entitled the "Bursa Municipal Statute", dated 1502 and still existing in the Archives of the Topkapı Palace, constitutes a decree Sultan Beyazıt II, determining the standards, of various articles and products and setting forth the basis for their implementation. The said document covers many varieties of agricultural and industrial goods ranging from foodstuffs to textile products and from hides and leather to shoes. The royal decree also

presents a system that is quite similar to the advanced standard of our days; specifying the characteristic of the raw materials for each of the above mentioned items, their production methods and control conditions as well as even the effects there of on the cost.

The standardization activities, dealt with due importance and with today's concepts during the ascension period of the Ottoman Empire. After the discovery of steam engine and of the Ottoman Empire not being able to keep pace with the great industrial development taking place in the West, the standardization activities gradually lost their importance and finally disappeared completely in time.

2.2 THE REPULICAN ERA

Among its other great advances, The Republic of Turkey, set up in 1923, also took up the matter of standardization, and renewed the effort to establish a market arrangement by means of the "Statute Regarding Prevention of Fraud and Adulteration in Commerce and Control of Exports", accepted in 1930 and bearing the number 1705.

Those who were striving to further the standardization movement in Turkey, followed in Atatürk's footsteps, as was the case in all other matters,and took as their starting point the principles he underlined in his keynote

adress of the 5th Session of the Grand National Assemby of Turkey, on 1 November 1937.

After the passage of statute 3018, forming an annex to Statute 1705, in 1936, a special standardization department was set up at the Ministry of Economy and Trade of the time. The said department provided important developments in the exports of Turkey. During the said period, the work of drawing up and applying standards had been administered under the responsibility of the state.

In the years following World War II, the matter was taken up seriously anew in Turkey, as was the case in a great many countries, with a new concept.

Faced with the creation of international standardization organizations such as ISO and as well as with the increasing advance and importance of technique and of commercial relations, a new institution was undertaken.

2.3 TOWARDS THE TSE

The Turkish Standards Institution, which was set up in 1954 within the body of the Union of the Chamber of Commerce, Chambers of Industry, and Commodity Exchanges, oriented itself towards achieving positive result despite its very small staff and very limited financial possibilities but accomplished a modern standard institute. In 1960 a law No:132 was published by the parliament in line with

the rules and regulations set up by its founders in 1954.

2.4 FORMATION AND PURPOSE

Article 1 - The "Turkish Standards Institution" has been set up for the purpose of drawing up standards for all kinds of goods and products as well as for methods and services.

The Institution is a public institution having Juridical personality and being administered according to the provisions of private law and its acronym and trade mark is "TSE".

Only the standards accepted by the Turkish Standards Institution shall be called "Turkish Standards".

The said standards shall be optional, and may be rendered mandatory upon the proposal of TSE and approval by the Ministry concerned. In order for a standard to be rendered mandatory it shall be essential for it to be a "Turkish Standard".

2.5 DUTIES

Article 2- The duties of the Turkish Standards Institution are as follows :

A - Drawing up and causing to be drawn up all kinds of Standards.

B - Examining Standards drawn un within the body of the Institution or outside and accepting them as Turkish Standards if found suitable,

C - Publish the accepted standards, encouriging their application optionally and submitting those, the mandatory application of which are deemed useful to the ministries concerned for obtaining a ministerial decree for their mandatory implementation.

D - Upon request of the private and public sectors drawing up standards or preparing projects and providing opinions thereon,

E - Carrying out all kinds of scientific and technical studies in the matter of standards, following up similar work carried out in foreign contries, establishing relations with international standardization organizations and cooperating with them,

F - Ensuring cooperation with the universities and with other scientific and technical institutions and establishments, issuing publications on standardization subjects, setting up archives of national, and international and intergovernmental standards.

G - Constituting laboratories for the purpose of research in connection with drawing up standards as well as for controlling the implementation of the standards; carrying out the technical work demanded by the public or private sector and issuing reports thereon,

H - Training personnel for establishing and developing standard affairs in the country, and conducting courses and seminars for this purpose,

I - Carrying out all kinds of work and drawing up the necessary certificates in order to promote the production of goods of high quality and in compliance with the Turkish Standards.

The arrangement of these duties of the Turkish Standards Institution, on a priority basis, shall be determined by its General Assembly and Communicated to those concerned.

2.6 ORGANS OF THE TSE

The organs of the Institution that will carry out these duties are :

1 - The General Assembly
2 - The Technical Board
3 - The Board of Directors
4 - The Inspection Board
5 - The Specialization Boards
6 - The Secretary-General and Staff

The Manner in which these organs are to be formed as well as their duties and working methods are indicated with all details in the "Turkish Standards Organs Regulations"

2.7 LABORATORY WORK AT THE TSE

The TSE laboratories are in five main groups :

1 - Electrical Laboratory

2 - Electronic Laboratory

3 - Chemical and Materials Laboratory

4 - Machinery and Construction Laboratory

5 - Packaging Laboratory

- Carrying out the researches connected with the stan ards to be drawn up.

- Carrying out tests on the samples taken by the Comptrollers of the Ministry of Industry and Trade during the execution of the Turkish Standards which had been put into mandotory implementation.

- Fulfilling the duty of "Arbitrator Laboratory" in public purchases.

- Carrying out the laboratory examinations and tests especially connected with the contracts enacted by the TSE with various firms for the utilisation of the "TSE Mark", drawing up the reports thereon, and enduring the enforcement of the said reports.

- Carrying out the examinations and tests connected with the Qualiy Document.

2.8 MARK AND CERTIFICATION WORK

The TSE Mark : Parallel to the implementation in the industrially advanced countries, in Turkey also the mark denoting conformity with the standards is issued by our Institution within the framework of the provision of the Formation Statute.

The producers and manufacturers, who have confidence in the quality of the food products they put on the market and who possess adequate means, apply to the TSE and demand announcement to public opinion that their products conform to the standards concerned, and if the investigations and evaluations carried out by the TSE auditors yield positive results, contracts are enacted providing for the registered TSE Mark to be allowed to be put on the said goods. Thus the buyers who see the TSE mark on the goods are able to buy these food products with faith and confidence.

Foreign manufacturers may obtain TSE Marks for their products if the goods comply with the relevant Turkish Standards.

Certification Work : The duty and authority of issuing all kinds of certificates are granted to the TSE.

- Certificates of Conformity to Standards
- Certificates of Manufacturing Adequacy
- Quality Certificates
- Certificates of Conformity to Special Conditions

2.9 PREPARATORY GROUPS

These are the organs that are authorized in the matter of drawing up and causing to be drawn up standards on various subjects. The preparatory Groups presently working at the TSE are as follows:

1. Agriculture Preparatory Group
2. Chemical Preparatory Group
3. Construction Preparatory Group
4. Ecological Preparatory Group
5. Electrical Preparatory Group
6. Electronics Preparatory Group
7. Engineering Services Preparatory Group
8. Forest Products Preparatory Group
9. Health Preparatory Group
10. Laboratory Preparatory Group
11. Machinery Preparatory Group
12. Metallurgy Preparatory Group
13. Mining Preparatory Group
14. National Defence Industry Preparatory Group
15. Petrochemistry Preparatory Group
16. Petroleum Preparatory Group
17. Processed Foods Preparatory Group
18. Special Standards Preparatory Group
19. Textile Preparatory Group

2.10 FOREIGN RELATIONS OF TSE

-Relations with International Organizations

-Relations with Regional Organizations

-Bilateral Relations

TSE is a member of the ISO and IEC, the TSE is the only organization to represent Turkey in the work on international standards.

Because of this characteristics, the TSE is the only organization, the views of which are sought in the preparation phase of international standards, and which evaluates whether or not a standard being drawn up conforms to Turkish Conditions and reports it view there on accordingly.

The TSE is also a full member of the European Organization for Quality Control. (EOQC)

2.11 LIBRARY AND DOCUMENTATION

The Library and Documentation Center can provide through its Foreign Standards, Sales Service, which is incorporated in its structure, International IEC and ISO Standards, National Standards of foreign countries, National Standards, Military Standards, the ASTM-API-ASME-VDE standards of institutions that draw up standards on special subjects, as well as the standards of the European Economic Community (EEC) and the FAO standards of the United Nations.

2.12 IMPLEMANTATION OF STANDARDS IN TURKEY

The application of Turkish Standards, which are drawn up and published by the TSE according to definite methods, is optional in principle.

Upon proposal by the TSE, the ministry concerned renders the standards it deems necessary mandatorily valid on the basis of Statute No 132 by taking into consideration the economic policy of the Government as well as the control possibilities, and conformity with such standards by all those concerned acquires a mandatory character.

Voluntary Compiance to TSE standards by manufacturers can be obtained from TSE by a certificate of conformity to TSE.

Topics for Health Preparatory Group in 1985-1986 are given in Appendix 4.

The list of standards related to biomedical equipments and supplies until 1984 is given in Appendix 3

III. INTERNATIONAL STANDARDIZATION FOR MEDICAL DEVICES

3.1 IEC (INTERNATIONAL ELECTROTECHNICAL COMMISION)[3,13,14]

IEC is the organization responsible for international standardization in the electrical and electronics fields. IEC was formed in 1904 as the result of adoption by the Chamber of Government Deputies at the St.Lois International Electrotechnical Congress of the resolution: "Steps should be taken to secure the cooperation of the technical societies of the world by the appointment of a representative commission to consider the question of the standardization of the Nomenclature and Ratings of Electrical Apparatus an Machinery" The IEC is presently composed of 45 National Committees that collectively represent some 80 % of the world's population that produces and consumes 95 % of electric energy.

The National Committees are expected to be fully representative of all electortechnical interests in their respective countries. These interests include manufacturers, users, trade associations, government and the academic and engineering professions.

The work of the IEC is carried out by the Technical Committees and their Sub-Committees, each responsible for developing standards for a well - defined sector of technology. At 1 st January 1983, 205 such Committees were active practically in all fields of electrotechnical.

The IEC standards are widely adopted by the members of National Committees as the basis of their national electrotechnical standars so far as local customs and conditions permit. They are also quoted in manufacturers specifications and by users, for instance, when calling for tenders. This widespread adoption facilitates inte na- tional trade in the electrical and electronic engineering sectors.

The IEC works in close Co - operation with the ISO.

IEC documents are called recommendations, not standards. They are processed, published and sold in much the same manner as ISO documents.

The IEC Technical Committee 62 on Electrical Equipment Used in Medical Practice is the primary committee concerned with medical equipment.

The IEC 62 has four major subcommittees:

1. IEC SC 62 A : Common aspects
2. IEC SC 62 B : X ray equipment
3. IEC SC 62 C : High energy and nuclear medicine
4. IEC SC 62 D : Electromedical equipment

Subcomittee SC 62 D, Electromedical Equipment, of the IEC has adopted an approach to its work that focuses on restrictive requirements for safety issues, while leaving performance to a disclosure approach.

3.2 CLARIFICATION OF THE TYPE, PURPOSE AND CONTENT OF STANDARDS PREPARED BY IEC SC 62 D

The first priority types of medical electrical equipment, and as necessary, to write performance standards which would require the disclosure of performance in a specified way. Test methods would be specified in order that the manufacturer could be tested in a uniform way.

Three types of IEC standards for medical electrical equipment are recognized. These are:

1. The General Standard - IEC 601 - 1: This is IEC 601 Part 1 which specifies the general requirements for the safety of medical electrical equipment and is the basis for the special safety requirements for certain types of equipment which are specified in Particular Safety Standards. (IEC 601 Part 2)

2. Particular Safety Standards (IEC 601 - 2): Each standard specifies the minimum safety requirements for a particular type of medical electrical equipment and must be read in conjuction with IEC 601 - 1 , the requirements of which, are supplemented or amended as necessary by the Particular Standard which is a Part 2 of IEC 601.

The requirements of a Particular Safety Standard take precedence in the case of the equipment concerned, over those of the General Standard.

A Part 2 standard is concerned only with safety and it should, therefore, contain only those requirements and compliance tests deemed necessary to ensure the safety in use of the particular type of equipment covered by the standard. In addition to any necessary amendments to the basic safety requirements of the General Standard, a Particular Safety Standard must also specify limits for those performance parameters that directly affect safety, e.g., the maximum allowable charging time of a cardiac defibrillator. These parameters directly affect safety that a manufacturer's disclosure alone is regarded as inadequate.

Performance parameters which do not directly affect safety, e.g. , the band width of an ECG recorder, must not be specified in a Part 2 (Safety) Standard. If necessary they must be specified in a Part 3 of IEC 601 (Particular Performance Requirements)

3. Particular Performance Standards (IEC 601-3)

The rate of development in medical electrical equipment is so rapid that a draft standard which incorporates rigid performance requirements is likely to be obsolete before it can be published. Therefore a Particular Performance Standard (IEC 601 Part 3) should normally not attempt to specify minimum levels of performance but should

require the manufacturer to disclose the performance of the equipment in a specified wayin order that users, manufacturers and test authorities alike may have a common understanding of the paratemeters concerned.

A part 3 Standard will specify the terminology and definitions applicable to a particular type of medical electrical equipment and will also specify tests in order that a manufacturer's declared performance may be tested in a uniform an acceptable way.

Performance parameters which directly affect safety must not appear in a Part 3 standard but should be specified in the relevant Particular Safety Standard. (IEC 601-2)

IEC SC 62 D has also adopted the practice of including rationale in its standards. IEC standards for medical electrical equipment pay particular attention to mandatory application issues, as they are being incorporated, by reference, into the regulatory systems of major European countries.

The Technical Committees of the IEC are given in Appendix 5.

The Medical Device Committees of IEC are given in Appendix 6.

The list of IEC Standards is given in Appendix 7.

IV. THE MEDICAL DEVICE REGULATIONS IN CANADA[4]

In Canada, enabling legislation to prevent the sale of hazardous or ineffective medical devices has existed since 1954 in the form of the Food and Drugs Act. According to the act, it is an offense to sell a device that is unsafe when used according to instructions; that does not perform according to claims; or that is mislabeled, contaminated or not in compliance with a mandatory standard. These powers were used in fifties and sixties to cope with specific device concerns. In 1974, however in recognition of the increasing importance and complexity of technology in medicine and the consequent need for a formal device program, the Health Pratection Branch of the Department of National Health and Welfare established the Bureu of Medical Devices in the Environmental Health Directorate. In September 1975, the Medical Devices Regulations were passed to outline specific requirements. These regulations require a manufacturer or vendor of a device to inform (notify) the bureau regarding what is sold in Canada, to ensure that the product

is adequately labeled, and to make available in Canada test results supporting basic performance and safety aspects of the device. Records of all problems reported and of corrective action taken must be maintaned, and the bureu must be informed recalls and similar actions.

The bureau's notification files contain information on more than 275.000 currently available devices, as well as on a very large number that are no longer sold but are still in use and occasionally modified. Accordingly, bureau activities can be grouped under three headings: premarket review, standards, and problem resolution .

On October 7, 1982 , the Medical Devices Regulations were amended to prohibit sale of a new implantable device unless a Notice of Compliance has been issued for it.

To obtain a Notice of Compliance , a manufacturer must submit for evaluation data establishing the safety and effectiveness of the new device. The bureau has issued a guideline to aid in the preparation of such submissions. A notice of Compliance does not signify approval, but it provides assurance that appropriate tests demonstrating reasonable probalibilty of safety and effectiveness in humans have been carried out. A list of devices that have received Notices of Compliance will be published annually to assist users.

The standards work of the bureau serves to develop performance and safety requirements and testing capability.

Mandatory standards may be prescribed to carry out the provisions of the Food and Drugs Act.

Standards are developed in colloboration with national and international agencies, manufacturers, and health-care personnel. Mandatory performance or disclosure standards are in force for contraceptive devices, cardiac pacemakers, portable emergency oxygen inhalators, evacuated blood collection tubes, disposable insulin syringes and current limits in electromedical devices. Standards are being developed for incubators, sphygmomanometers, anesthesia systems, gas outlets, ozone-emitting devices, color coding of medical gas handling devices, hospital cribs and several in vitro diagnostic products.

Guidelines, interpertations of regulations and criteria documents are also issued for the guidance of both manufacturers and users.

V - THE STANDARDS FOR BIOMEDICAL DEVICES IN THE USA[3,18]

5.1 INTRODUCTION

Activity in medical device standards has accelerated rapidly since the late 1960s because of an increase the Food and Drug Administration (FDA). In the voluntary area, the American Society for Testing and Materials (ASTM), the American Dental Association (ADA), and the Association for the Advancement of Medical Instrumentation (AAMI) have been the principal organizations concerned with medical device standards. AAMI is a recent entry into the standards area while the other two organizations have been in existence for years.

As the interest was stimulated in the medical device area, the FDA responded by catologing the various standards programs directed at medical devices and semiannually publishes the Bureu of Medical Devices Standards Survey: Both a national and an international edition is published yearly in July and January respectively.

The NFPA and Underwrit r's Laboratory (UL) standards activities have received widespread attention, primarily

because of the listing for certification by the UL and by the adaption in many localities of the NEC which is developed under the auspices of the NEPA.

Efforts to develop standards and specificitons for medical devices in the USA are divided between government and voluntary agencies. Standards efforts by voluntary organizations have been fragmented and did not become a mojor force in the medical device standards area until the early 1970s. In a few areas cooperative efforts between the gowernment and voluntary organizations evolved. The Voluntary Product Standards Program of the NBS is one such example. A full-time director and technical staff at the NBS exemines dental materials and equipment. The American Dental Association and the ANSI Dental Standards Committee have been active since the mid-1960s developing ANSI dental standards.

5.2 U.S. GOVERNMENT ORGANIZATIONS

The governmental agencies and programs for medical device standards are :

1. The Bureau of Medical Devices within the FDA is responsible for the development of medical device and invitro diagnostic product standards and their promulgation as specified undur PL 94-295, the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act.

2. The Bureau of Radiological Health, also within the FDA, is responsible for administering the Radiation and Control for Health and Safety Act. PL 9602.
In medical field, X-ray equipment, laser devices ultrosonic equipment.

3. The Federal Communications Commission (FCC). Devices such as X-ray, diathermy and ultrasonic devices fall under the jurisdiction of FCC.

4. The Occupational Safety and Health Administration (OSHA) of the Department of Labor facuses on safe working conditions for hospital employees.

5. The National Bureau of Standards (NBS) provides reference standards for calibrating medical and other instruments.

6. The Veterans Administration (VA) primarily establishes standards for its purchasing of biomedical instrumentation.

5.3 TRADE ORGANIZATIONS

The primary organizations are : The Pharmaceutical Manufacturers Association (PMA), The Health Industries Manufacturers Association (HIMA), the Scientific Apparatus Manufacturers Association (SAMA), and the Compressed Gas Association (CGA). Tese organizations play a useful role in consolidating and providing a consensus of the manufacturers' wievpoints on various standards and activities.

5.4 PROFESSIONAL ORGANIZATIONS

Various professional organizations play a role in the development of standards. Such organizations as the American College of Cardiology, the American College of Surgeons, and the American College of Neurosurgeons have committees that deal with medical device standards. These organizations primarily provide participants to voluntary organizations such as ASTM and AAMI.

5.5 FEDERAL PROGRAMS

The medical device standards and specifications activities sponsored by the federal government are extensive. They represent the largest standards effort in the nation under a single organizational structure. However, federal efforts are not a single program but consist of a variety of seperate programs within different departments, agencies and military commands.

The agencies that are active in the medical device standards area include (VA) and the FDA. The Defense Personnel Supply Center (DPSC) is the largest purchaser of medical devices within the government and prepares a majority of the specifications and standards used in its procurement activities.

5.6 STATE AND LOCAL GOVERNMENT

Some of the most prominent examples used in this area are the Unterwriters Laboratories Inc (UL) listing, the NFPA and other independent laboratory evaluations of proprietary standards or existing Americal National Standards.

UL conducts testing and evaluation programs which result in listing of the device in accordance with standards that it develops. For biomedical equipment UL standard 544 (for safety of medical and dental equipment).

NFPA standards in the medical field usually are facility-oriented, but in some cases can involve specific medical devices. The following NFPA standards are applicable in the health care field.

1. Inhalation anesthetic standard NFPA 56A, specifies safe practices.

2. Respiratory therapy standard NFPA 56B, discusses treatment with oxygen, artificial ventilation, etc.

3. Essential electrical systems standard NFPA 76A details safe practices for hospital electric power, wiring, and emergency power.

4. Electricity in patient-care facilities standard NFPA 76B-T recommends safe practices for hospital electric wiring, installation, electrical appliances and inspection.

5. High-frequency electricity in health-care facilities standard NFPA 76 C, presents safe practices for use of electrosurgery and diathermy equipment. Also there are some other NFPA hospital standards available from the NFPA.

Canadian Standards Association publishes a series of codes that cover subjects similar to those of the NEPA.

Laboratory evaluation : There are various laboratories throughout the U.S. that test and evaluate medical devices. Many states have rules that apply to purchase by their state hospitals. In addition, many states have adopted regulations applicable to medical equipment.

5.7 STANDARDS FOR THE OPERATION OF HOSPITALS

The Joint Commoission on Accreditation of Hospitals (JCAH) establishes standards for operation of hospitals. Hospitals that volunteer to be accredited request on accreditation survey. They are expected to meet the standards set forth in the Accreditation Manual for Hospitals (JCAH, 1976). Compliance with standards is assessed by statements given by hospital personnel, documentary evidence, answers to detailed questions, and on-site observations by surveyors.

5.8 RADIOLOGICAL REGULATIONS

Radiological regulations can be classified in to three general groups : federal, state, and professional bodies.

5.8.1 Federal regulations

The applicable sections of the Code of Federal Requlations is title 10 for the Nuclear Regulatory Commission rules on isotopes sources and title 42 for the Food and Drug regulations concerning X-Ray machines and electron accelerators (Code of Federal Regulations, 1977). An additional source of guidance are the Regulatory Guides published by the Nuclear Regulatory Commission (U.S. Nuclear Regulatory Commission, 1977)

5.8.2 State Regulations

Generally the state regulations closely follow the federal regulations.

5.8.3 Professional bodies

Examples are the JCAH (1976), National Council on Radiation Protection (1977), International Council on Radiation Protection (1977) and the International Commission on Radiation Units and Measurements (1977).

5.9 GOVERNMENT DEVELOPMENT OF STANDARDS

The key organization for the development and promulgation of medical device standards is the Department of Health, Education and Welfare, FDA, Bureau of Medical Devices.

Under the medical devi e amendments, three device classes are established for the control of devices intended for human use (FDA, 1977). Clas I is considered general control (controls at the lowest level) and applies mainly to provisions reflecting the labeling of a device, registration of device manfacturers and the keeping of records and reports. The next higher class of regulatory control is Class II performance standards. If the provisions of Class I are not sufficient to provide for the safety and efficacy of the device, it is placed under Class II performance standards. The highest regulatory control class is Class III, premarket approval. Class III devices must undergo premarket approval prior to being placed on the market.

VI. THE MEDICAL DEVICE REGULATIONS IN EUROPE [4,17]

6.1 INTRODUCTION

The Medical device industry in Europe is today confronted by a perplexing variety of rules, regulations, laws and requirements, some on the status, some in draft, some still in the minds of their sponsors. The purpose of this part is to bring the reader up to date on spesific regulatory developments in key European countries, to examine the extent of and constraints upon Industry- government interaction in some of those countries .

European Regulatory Update:

In certain countries significant modifications are being made in the regulations affecting a number of medical device categories.

6.2 FRANCE

Since 1950, France has had a system of homologation (offical approval) for medical technical equipment reimbursed

by its Social Security system. Until recently, approval had been granted by an interdepartmental commision. There were various product-specific requirements, specifizations, and procedures for testing stipulated by decree or norm. On January 5, 1983, an entirely new scheme was introduced. It is not yet clear how the details will be worked out, but the interdepartmental commission has been abolished and a National Committee of Homologation has been created with in the Ministry of Health. This committee has full responsibility for the approval procedure. Five subcommittees have been appointed to oversee the categories of imaging, operating theatres, atificial organs and prostheses, anesthesia and reanimation, and diagnostic equipment and monitoring. Experts drawn from the minitries, hospitals, and Universities have been named to these subcomimmitees, which are charged with defining the detailed homologation procedures.

The primary contact for suppliers and manufacturers will be the Centre National de L' Equipments Hospitalier (CNEH), which is responsible for managing the product dossiers submitted and carrying out the technical testing. In addition to these tests, manufacturers will be obliged to undertake clinical evaluations in designated French hospitals, as well as to incorporate compulsary quality controls into the manufacturing process.

6.3. WEST GERMANY

The two key laws in West Germany are the Drug Law

of August 24, 1976, and the Law on Technical Equipment and Devices of June 24, 1968 as amended August 13, 1979. The Drug Law, which is administered by the ministry of Health, concentrates on the safety and efficacy of drugs traded in West Germany and has only limited application to medical devices. However, implantables are brought within the scope of the legislation once they are actually implanted. The Ministry of Health has statutory responsibility when problems with such products are reported and corrective action is necessary. This law may be extended to cover medical devices at any time by ministerial action through a statutory order.

Section 8 of the Technical Equipment and Devices Law, amended empowers the federal Ministry of Labour and Social Welfare to stipulate in a statutory order that technical appliances for medical use may be brought into circulation or be exhibited only if they comply with certain requirements or conditions. Under this provision, a Statutory Order on Safety of Technical Appliances for Medical Use has been published in draft (Referentenentwurf, November 20, 1981) This order concentrates on power-driven, including ultrasonic Doppler flow meters, electro and phono cardiographs, blood pressure meters, defibrillators, appliances for intravascular examination and control, appliances for the diagnostic and therapeutic stimulation of nerves and muscles, electroconvulsive - therapy appliances, photo and laser coagulators, high-pressure injection syringes, cyrasurgery appliances, infusion and syringe pumps, perfusion pumps, respiration appliances, incubators, pacemakers,

dialysis appliances, hypotermia appliances, heart /lung machines, laser surgery devices, and blood filtration devices.

The order sets forth general requirements with regard to the construction of all affected medical appliances.

A design permit, granted by a state - approved test house (TUV) , is required before the products can be marketed. There are also special training and safety regulations derived form the Industrial Code that apply to the operators of such medical appliances. The responsibilty for establishing detailed technical regulations implementing the provisions would be delegated by a committee to be established under the order to subcommittees of experts to be appointed for each product area. The draft order is expected to be formally laid before Parliament during the summer of 1983. If adopted its effective date would be January 1985.

6.4 ITALY

Italy's basic law on medical devices, possed in 1927, has developed around products in contact with the blood. The Italien Ministry of Health, through its pharmeceutical division, is now completely updating and overhauling the legislation. It is proposing a twotier approach of an overall regulation for medical devices and detailed standards or norms to be established for particular products. Under the proposed Medical Devices Law, products would be divided into groups, and compliance with different group- specific rules

with regard to registration, controls, product modification, and so forth would be required before a Licance would be granted allowing the sale of a medical device.

6.5 THE NETHERLANDS

Historically, the Dutch government has taken a very pragmatic approach to medical device legislation based upon a recognition that the costs to society of government regulation often outweighed the benefits. Nevertheless, this relatively regulation-free environment for suppliers and manufacturers is now being changed. Effetive January 1, 1984 new producers controlling sterile medical products are introduced. They regulate sterilization processes, both in the hospital and by the supplier or contractor , and trade (including a requirement that suppliers of sterile devices be licensed). It is the intent of the Ministry of Health, the responsible authority, to build up a data bank on suppliers and pruducts by the registration scheme to be established under the new procedures.

6.6 UNITED KINGDOM

The unique nature of the British National Health Service has dictated the development of regulations affecting medical devices. In contrast to the approach for drugs and medicines, which requires full premarket evaluation under the Medicines Act of 1968, the Department o

Health and Social Services (DHSS), through its scientific and Technical Branch, has chosen to exert its authority indirectly through the purchasing process and through its influence on decisions made at the hospital level. In mid- 1982 DHSS instituted voluntary good Manufacturing Practices GMP s as the cornerstone of its regulatory ccntrol of manufacturers of medical devices. A "Guide to Good Manufacturing Practices" is available, written in terms of broad principles, expanded notes and clarifications can also be provided according to product. DHSS has also established a registratiton scheme for manufacturers, since it is they who must implement the GMPs . One of the aims of this under taking is similar to one of those of the Dutch: to build up a complete record of products manufactured for sale in their jurisdiction. Should the current voluntary scheme prove ineffective , section 104 of the Medicines Act provides for residual authority to extend that statute to medical devices as well.

6.7 OTHERS

It should be remembered that other nations also have recently introduced regulations concerning medical devices (an example is Norway.), and countries such as Spain Sweeeden have revived their interest in seeking compliance with regulations that have been on the statute books for some time.

VII. PRODUCTION OF MEDICAL EQUIPMENT IN TURKEY AND RELATED STANDARDS[1,2,10,11]

7.1 A SURVEY ON MEDICAL PRODUCTION IN TURKEY

A survey is carried out on local production of medical equipment and instruments in Turkey. This survey indicates 26 manufacturers for medical equipment in Turkey. Out of this 26, 8 are related in dentistry equipment, such as: Teeth units and sets', dental prothesis laboratory, compressor, dental chairs, dental X-ray units. The remainder 18 companies are producing mostly syringes, gynecological and surgical tables, disposable materials for hospitals and clinics.

There are two tables for this survey:
The list of the products in Turkey and the ones that have Turkish Standard and their manufacturers is in TABLE 1.

The adresses of the companies indicating their production are in TABLE 2.

TABLE 1

The medical intruments and hospital equipment manufactured in Turkey , the ones that have TSE Standard and their manufacturers:

Note:

* *The TSE Standard is available*

∇: *The TSE Standard shall be drafted by 1986*

	Manufacturer No: (Refer to Table 2)
1. * Teeth units and sets	9, 11, 25
2. Dental X-ray units	6, 9
3. * Dental units, arm chairs, elevators	6, 9, 21, 25
4. Aerator	21, 25
5. Airfilter	15
6. Compressor	15
7. Aspirator	1, 15, 21
8. Crescoire	15, 21
9. Cupboard system for dentistry	23
10. Dental prothesis laboratory	19

		Manufacturer No: (Refer to Table 2)
11.	Vacuum extractor , vacuum curette system	1
12. *	Syringes	10, 14, 17, 20
13.	Gynecological and surgical tables	12, 23, 25
14.	Hospital beds	12, 23, 24
15.	Upholstery for hospital use	12, 23
16. ∇	Cupboards	12, 23
17.	Lightining systems	12, 23, 25
18.	Traction tables	4
19. *	Disposable materials for hospitals	10, 14, 17, 20
20.	Laboratory diagnostic reagents and chemicals	
21. *	Medical Plastes	16
22.	Uninterruptible power systems for hospitals which cannot tolerate any power interruption	
23. *	Microscopes	
24.	Oxygen tents	
25. ∇	Baby cots	4
26. ∇	Dry air stelizer	
27. *	Some sorts of surgical instruments	
28.	Springhose	15
29.	X-ray surgical aspirators for surgery	
30.	Myth light (for density, gyn ecology, gastrointereology)	

		Manufacturer No: (Refer to Table 2)
31.*	Laboratory glassware and glass tubing for pharmaceutical uses	26
32.	Vacuum bottles for central systems	
33.*	Stainless steel varieties instrument boxes	12
34.*	Silk, linen, braided ar monofilament synthetic suture.	13
35.	Bed sore prevention system	1
36.	Baby incubators	4, 8
37.	ECG monitor with recorder and hearth rate meter (Heart-beat monitor)	5
38.	ECG monitor with blood pressure	5
39.	Coronary care systems	5
40.	Various types of bed-side monitors	5
41.	High frequency surgical units	5,3
42.	Heater / Cooler equipment (for heart-lung machine)	1
43.	Fetal detector	3
44.	Artifical kidney machines(Hemodialysis unit) solitons, coils and sets	18
45.	Parentereal solutions in PVC bags and peritoneal dialysis solutions	18
46.	Acupuncture devices	2
47.	Physical therapy equipment accessories	2,5
48.	Ultrasound therapy device	5
49.	Ethylen oxide gas sterilizer	3
50.	Diadynamic therapy device	5

		Manufacturer No: (Refer to Table 2)
51.	Accessories for electrosurgery	2
52. ▽	Sphygmomanometer	
53.	Electrodes for ECG	2
54.	Spectrophotometer	3
55. ▽	pH - meter	3,22
56.	Laboratory and clinical centrifuges	8
57.	Autoclave	
58.▽	Humidifiers	
59.▽	Stethoscope	
60.▽	Cathater	
61.	Gama counter	7
62.	Rotator	7
63.	Reflector	15, 25
64.	Opthalmic unit	3
65.	Pyrogen Test	3
66.	Flame Photometer	3

TABLE II

The medical instruments and hospital equipment manufacturers in Turkey and their production:

BIÇAKÇILAR, Tıbbi Cihazlar San. ve Tic. A.Ş.

Merkez : Yeniçeriler Cad. 44 - Çarşıkapı/İST. Tel: 5267624

Fabrika : Keresteciler Sitesi - Merter/İST. Tel: 5844851

İrtibat Bürosu: Sağlık Sok. 25/4 Sıhhıye/ANK. Tel: 310947

PRODUCTION

1.1 Vacuum Extractor

- Vacuum bottle : 1,5 L , 2x1,5 L
- Vacuum Power : 0-700/740 mm Hg
- Mobile, foot pedal controller
- Controlling vacuum by monometer
- Fully-automatic

1.2 Vacuum Curettage System

- Vacuum control by monometer
- 8,9,10,11,12 mm vacuum curettage points
- Vacuum power : 0-700/740 mm Hg

1.3 Surgical, Portable Aspirators

- 250 W, monophase electric motor (220V, 50Hz, 3,8 A)
- Vacuum Power : 0-700/740 mm Hg
- Vacuum bottle : 2L, 2 x 1,5L, 2x3L
- Weight : 35-50 kg
- Foot - pedal (on-off)

1.4 Continious, intermittent Aspirator

- 1,5L bottle, 0-15 mm.Hg vacuum power
- Controlling vacuum by monometer
- Continious operation, Auto on/off intervals

1.5 Bed sore prevantion system

- Bed : 73 x 195 cm, time control unit and compressor
- Weight : 8 kg

1.6 Oxygen therapy equipment

- Gas controlling : 0 - 15 L/min
- Monometer, security valve, O_2 humidifier and flowmeter

1.7. Vacuum bottles for central system (3-1,5 L)

1.8. Heater / Cooler equipment (for heart - lung machine)

2. BÜLBÜL Medikal

Şehit Teğmen Kalmaz Cad. Modern Çarşı 3-417 ANK.

Tel: 241778

PRODUCTION

2.1 Acupuncture device

- 2 and 5 outputs, 3 channel frequency
- Also with battery , silver and galvanic needles.

2.2 Physical therapy equipment accessories

- Electrodes, coaxial cable, disc, rectal , rubber band

2.3 ECG accessories

- Metal electrodes, rubber band, ECG paper, patient cable

2.4 Sterilized Lamp (15 / 30 W)

2.5 Electrocotter accessories:

- Bipolar points, cables, 8,16 controlled interruptor
- Foot - pedal controller

3. EKOL Endüstriyel Kontrol ve Otomasyon Ltd. Şti.
Samsun Yolu, 48 / ANKARA Tel: 491684

PRODUCTION

3.1 pH - Ion Meter

- Digital display range : 0.00 - 14.00 pH
- Can be used as ionmeter with spesific ion electrode
- Electrode heat compensation and slope control

3.2 Electrosurgical unit - (400 s)

- RF Output power : 400 W max.
- Unipolar bipolar use, audio-vision alarm
- Blend cut use (cutting and coagulation)
- Different volume for cutting, coagulation and bipolar output

3.3 Fetal detector

- 8 hours of non-stop operation (chargeable)
- Able to detect the heart beat of 7-10 weeks fetal
- Audio - output, accessories bag

3.4 Ophtalmic unit (Cyro device)

- CO_2 and nitrogen tubes, too short defrost time
- Able to operate at ($-70^{0}C$)
- Analog and digital display for showing temperature and gas pressure

3.5 Pyrogen test

- Electronic and digital thermometer to detect pyrogen in rats by rectal thermal change

3.6 Spectrophotometer - (Spectrokol 100 D)

- λ= 340- 910 nm (single beam)
- Detector: Wide - range photo diode

3.7 Ethylen oxide gas sterilizer - (EO 45)

- Automatic heating and time control, vacuum processes
- Ventillation unit makes possible to seperate gas from the material

3.8 Flame photometer - (Flamekol 1)

- Operation with propane and likid - gas
- Digital display reading for sodium, lithium

4. MEDA - Atakan Cad. 15/2 Sanayi/ANKARA

5. PETAŞ- Profesyonel Elektronik San. ve Tic. A.Ş
71. Sok. 21 Emek / ANKARA Tel: 137850
Şube: Barboros Bulv., 135, 1 Beşiktaş/İST. Tel: 1660908

PRODUCTION

5.1 High frequency surgical units - (400 s)

- Output power = 400 W , Coagulation : 120 W
- Blend 1: 320 W, Blend 2 : 240 W, Blend 3: 120 W
- Audio - visual alarm , Weight : 25 kg
- Dimensions = 45 x 19 x 38 cm.
- Bipolar coagulation = 500 Hz
- Operating frequency cutting/coagulation= 1000 kHz
- Bipolar coagulation remote control delay= 2 sec.

5.2 Ultrasound therapy device - (Model Petson 200)

- Audio output frequency = 1000 kHz±50 kHz
- Audio output power = 15 W
- Automatic time control= 0-15 min
- Output power intensity = 0,2/0,5/1/1,5/2/3 Watt/cm^2
- Electrical energy consumption = 40 W, Weight = 5 kg

5.3 Diadynamic therapy device - (Model Petdin 101)

- Diadynamic output current = max. 20mA
- Galvanic output current = max. 10m A
- Automic time control = 0-15 min
- Different diadynamic current waveforms.

5.4 Galvanic - faradic therapy device (Model - Petgal - 200)

- Galvanic output current = 100 m A
- Faradic current = 100 m A
- Total electrical consumption = 50 VA
- Different galvanic and faradic waveforms.

5.5 Interdifferential current therapy device

- 2 modes vacuum units and current generator
- Power consumption = 250 VA
- Output current = 0,75 mA
- Weight= 35 kg, various accessories
- Current forms = 0-100 Hz manual and automatic
- Impulse current waveforms= 50-100 Hz negative and positive scanning

5.6 ECG Monitor - (Cardiopet 110)

- Portable with recorder and memory
- Input Impedance : 20Ω, non-fade display
- Heart beat measuremen range= 20 - 250 beat/min
- Scanning and recording rate = 25 - 50 mm/sec.
- Patient leakage current = 15μA(rms)
- Derivations= CAL, I, II, III, V, AVR, AVF, AVL
- Electrical power consumption = Max 20 VA
- Nickel - Cd. , 12V, 1.8 A/hour

5.7 Complete coronary care systems

- Bed side monitors (2 channel, with memory)
- Central console and accessories
- Various monitors (with recorder, heart-rate meter, systolic, diastolic and average blood pressure)

6. RÖNTGEN - Elektromedikal Cihazlar Koll.Şti.

Hürriyet Tepesi, Dr.Cemil Bengü Cad. 33 Şişli/İST. Tel:482509

PRODUCTİON

Dental chair, X - rays equipment up to 50 mA

7. SESA ELEKTRONİK SAN. ve TİC. A.Ş.

Mithatpaşa Cad. 24/5 Kızılay / ANKARA Tel: 175749

İST. 1402558

PRODUCTION

Gamma counter , pH meter, centrifuge, rotator

8. NÜVE SANAYİ MALZEMELERİ İMALAT VE TİCARET A.Ş.

Kumrular Sok. 26/2 ANKARA Tel:302208 Tlx:49229 neltr

PRODUCTION

Laboratory and clinical centrifuges, ovens and incubators.

9. GÜNEY DİŞ DEPOSU TİC. ve SAN. A.Ş.

Beyaz Saray 9/B Beyazıt/İSTANBUL Tel: 5225004

10. BADEP TIBBİ ALETLER SAN. ve TİC A.Ş.

Çiçekpazarı,Yeni İş Hanı 6 Eminönü/İST. Tel: 5273772

11. BEYOĞLU DİŞ POLİKLİNİĞİ

Hamalbaşı Cad. 10 Galatasaray/İST. Tel: 1490670

12. DOĞU PAZARLAMA VE SATIŞ DEPOSU KOL.ŞTİ

İST: Millet Cad. Özbek Süleyman Ef. Sok. Aras Pasajı 41 Fındıkzade/İST.

ERZURUM: Belediye İş Hanı 8-9 Tel:111 31, 133 25

13. DOGSAN Cerrahi Dikiş Malz. Fb.

(Doğu Ecza Deposu A.Ş.)

Gazipaşa Cad. TRABZON Tel: 110 10/11 Tlx: 83147 doğu

Mollagürani Cad. 12 Fındıkzade/İST. Tel: 5259498/9

14. İLERİ METAL SAN. A.Ş.
    Çağlayan, Yurt Sok. 19- Şişli/İST. Tel: 1330512/13

15. KARYER DİŞ HEKİMLİĞİ CİHAZLARI İMALAT ve TİC. SOĞUTMA SAN.
    Mirmiran Sok. 16 - Dolapdere/İST. Tel: 1504892

16. SEDKO Bant-Kozmetik San. ve Tic. A.Ş.
    Ziya Gökalp Cad. 19 Maltepe -Kartal/İST. Tel: 3520295

17. SET
    Akarcası Sok. 20/2 Kasımpaşa/İST. Tel: 1506181

18. SİTAM TİC.
    Karanfil Sok. 30/6 Kızılay/ANK. Tel: 337248
    Fab. Esenboğa Karayolu 26 Km.

19. SOMADENTA Protez San. ve Tic. A.Ş.
    Mete Cad. 30 Taksim / İST. Tel:1440204

20. TIBSET Steril Tıbbi Aletler San. ve Tic.A.Ş.
    Kasımpaşa Akarcası Sok. 20/2 Kasımpaşa/İST. Tel: 1506181

21. TEKMİL SAN.
    Çayır Sok. 37/A Harbiye/İST. Tel: 1487837

22. NEL Nükleer Elektronik A.Ş.
    Sümer Sok. 42 ANKARA Tel: 301510 Tlx: 42229 nel tr

23. GALERİ TIP Tıbbi Teknik Cihazlar Tic. A.Ş.
IMÇ 1.Blok 1426 - Unkapanı/İST. Tel: 264679

24. Dr.ALTUN Tıbbi Cihazlar Üretim Tesisi
Çiftlikköy P.K. 107 Yalova/İST. Tel:4102

25. BKB Tıbbi - Teknik Cihazlar San. ve Tic. A.Ş.
Anadolu Cad. 37 Salhane/İZMİR Tel: 162689

26. CAM PAZARLAMA A.Ş.
Büyükdere Cad. Beytem Han 4-8 Şişli / İST.
Tel: 1461130 Tlx: 22509 camp tr

7.2 STANDARDIZATION AND QUALITY TESTING FOR BIOMEDICAL DEVICES IN TURKEY

In the Turkish medical market there are more than 60 companies. Approximately half of them manufacture and produce health-care devices. The others are importers. They are the representatives and distrubutors of foreign companies. Two different recommendations can be made: One for the import devices and the other is for the devices manufactured in Turkey.

1. For the import devices, IEC Standards might be recommended. There is a list of some in Appendix: 7 These can be provided " BU-Biomedical Engineering Institute Documentation Center " And the Appendixes: 10 and 11 are the examples of IEC Standards. In instances where international standards are adopted by national standard bodies, international standards enhance import of these products to the country. In cases where national interests differ from the international standards, national standards create barriers to foreign market entry.

The IEC prepared an international standard "IEC 601-1, Safety of Medical Electrical Equipment" This was issued in 1977, and many countries have now adopted it as their national requirement. But there is an important problem for the recommendation here: Development of an international standard is a very slow procedure. Health technology is changing rapidly. After a special standard

is ready, the device complying with this standard may be obsolete. An if a country has to import an obsolete medical equipment because it is in compliance with international standard, purchase cost of the product should be lower than its normal price.

2. Recommendation for the devices manufactured in Turkey: The situation for the biomedical devices manufactured and their standards is in its initial stage. The Turkish manafacturers mostly produce simple dental equipments, laboratory chemicals and upholstery and disposables for hospitals. Only a few companies manufacture potentially critical devices. And these don't TSE Standards.

Now, it's recommended a legal basis for the control and test methods of these critical devices. And this must be developed with experts drawn from the TSE, Health Ministry, hospitals ant universities for certain groups of medical devices. Due to health safety, Turkish standards on the following products can be tested by proper institutes until TSE Standard is developed. The following products are:

1. Baby Incubators
2. ECG Monitors
3. Blood Pressure Monitors
4. Sphygmomanometers
5. Aspirators
6. Traction Units
7. Electrosurgical Units

Most of the qualitative and quantative tests for the medical devices can be carried out in the laboratories of the Biomedical Engineering Institute in Boğaziçi University. Since most of the test apparatus and supplies are available including the relevant personnel. These test for the relevant devices are as follows:

1. The qualitative and quantative tests of BABY INCUBATORS:

I. Qualitative Tests:

1. Chassis / Housing
2. Mount / Fasteners
3. Casters / Brakers
4. AC Plug / Receptacles
5. Line Cord
6. Strain Reliefs
7. Circuit Breaker / Fuse
8. Tubes / Hoses
9. Cables
10. Fittings / Connectors
11. Probes
12. Filters
13. Contols / Switches
14. Heater
15. Motor / Fan
16. Fluid Levels
17. Battery / Charger
18. Indicators / Displays
19. Alarms
20. Audible Signals
21. Labeling
22. Accessories

II. Quantitative Tests

1. Grounding Resistance
2. Laakage Current
3. Specific Gravity of Battery Fluid
4. Skin Temperature Alarm
5. Safety Thermostat
6. Portable Power Supply
7. Hood Air Temperature Accuracy
8. Patient Probe Accuracy

2. The qualitative and quantative tests of ECG MONİTORS:

I. Qualitative Tests

1. Chasis / Housing
2. Mount / Fastaners
3. Casters / Brakes
4. AC Plug / Receptacle
5. Line Cord
6. Strain Reliefs
7. Circuit Breaker / Fuse
8. Cables
9. Fittings / Connectors
10. Electrodes
11. Controls / Switches
12. Battery / Charger
13. Indicators / Displays
14. lmV Step Response
15. Alarms
16. Audible Signals
17. Labelling
18. Accessories
19. Direct Writer

II. Quantitative Tests

1. Grouding Resistance
2. Leakage Current
3. Interlead Leakage
4. 120 V Isolation
5. Paper Speed
6. Rate Calibration
7. Rate Alarm

3. The qualitative and quantitative tests of

BLOOD PRESSURE MONITORS:

I. Qualitative Tests

1. Chasis / Housing
2. Mount
3. AC Plug
4. Line Cord
5. Strain Reliefs
6. Circuit Breaker / Fuse
7. Cables
8. Fittings / Connectors
9. Transducers
10. Controls / Switches
11. Indicators / Displays
12. User Calibration
13. Alarms
14. Pressure Modes

II. Quantitative Tests

1. Grounding Resistance
2. Leakage Current
3. Isolation
4. Accuracy, High(Arterial) Pressure Range
5. Accuracy, Low Pressure Range
6. Alarm Accuracy

4. The qualitative and quantative tests of SPHYGMOMANOMETERS:

I. Qualitative Tests

1. Chasis / Housing
2. Mount
3. Casters / Brakes
4. Tubes/Houses/Bulb
5. Fittings / Connectors
6. Filters
7. Bleed Valve
8. Indicators / Displays
9. Zero Pressure Setting
10. Labeling
11. Accessories
12. Gauge / Column

II. Quantitative Tests

1. Pressure Leakage
2. Gauge Accurayc

5. The qualitative and quantitative tests of ASPIRATORS:

I. Qualitative Tests:

1. Chasis / Housing
2. Mount
3. Casters
4. AC Plug / Receptacle
5. Line Cord
6. Strain Reliefs
7. Circuit Breaker/Fuse
8. Tubes / Hoses
9. Fittings / Connectors
10. Filters
11. Controls / Switches
12. Heater
13. Motor / Pump
14. Battery Charger
15. Indicators / Displays
16. Labeling
17. Accessories
18. Overflow Protection

II. Quantitative Tests

1. Grounding Resistance
2. Leakage Current
3. Maximum Flow Rate
4. Rate of Vacuum Rise
5. Maximum Vacuum
6. Vacuum Gauge Accuracy

And finally, medical device standards must affect hospitals from multimillion dollar NMR scanners to 25 cent disposable ECG Electrodes.

Hospital personnel need help to identify key standards of maximum importance. Biomedical engineers should learn about standards' procedures in general, so as to better participate in the development and revisions of the standards.

REFERENCES

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APPENDIX 1

THE ADRESSES OF NATİONAL STANDARDIZING ORGANIZATIONS

(91 Nations)

Algeria: INAPI, Institut Algerien de Normalisation et de Propriete Industrielle, 5 rue Abou Hamou Moussa, B.P. 1021, Centre de Tri, Alger

Argentina: IRAM, IRAM, Instituto Argentino de Racionalizacion de Materiales, Chile 1192, Buenos Aires

Australia: SAA, AS, Standards Association of Australia, 80-86 Arthur Street, North Sidney, N.S.W. 2060

Austria: ON, ONORM, Oesterreichisches Normungsinstitut, Leopoldsgasse 4, Postfach 130, A-1021 Wien 2

Bangladesh: BDSI, Bangladesh Standards Institution, 3-Dit (Extension) Avenue, Motijheel Commercial Area, Dacca-2

Barbados, W.I.: BNSI, Barbados National Standards Institution, "Flodden," Culloden Road, St. Michael

Belgium: IBN, NBN, *Institut Belge de Normalisation, 29 Avenue de la Brabanconne, B-1040 Bruxelles 4

Bolivia: DGNT, Direccion General de Normas y Tecnologia, Av. Mariscal Santa Cruz, Edif. Loteria, Piso 9, Casilla 4430, La Paz

Brazil: ABNT; NB, EB, *Associacao Brasileira de Normas Tecnicas, 13 Av. Treze de Maio, Andar 28, Caixa Postal 1680, CEP 20000, Rio de Janeiro

Bulgaria: DKC, State Committee for Standardization at the Council of Ministers, 21, 6th September Street, Sofia

Burma: UBARI, UBS, Union of Burma Applied Research Institute, Junction of Kaba Aye Pagoda-Kanbe Roads, Rangoon

Cameroon: Direction de l'Industrie (Service de Normalisation), Ministere du Developpement Industriel et Commercial, B.P. 1604, Yaounde

Canada: SCC, CAN, Standards Council of Canada, International Standardization Branch, Meadowvale Corporate Centre, 2000 Argentia Road, Suite 2-401, Mississauga, Ontario L5N 1P7

CSA, Canadian Standards Association, 178 Rexdale Boulevard, Rexdale, Ontario, Canada M9W 1R3

Chile: INN, Instituto Nacional de Normalizacion, Matias Cousino 64, Piso 6, Casilla 995, Correo 1, Santiago

China: CNS, CNS, National Bureau of Standards, Ministry of Economic Affairs, 5th Floor, Hsin Kuang Life Insurance Bldg., Taipei, Taiwan 104, Republic of China

Colombia: ICONTEC, Instituto Colombiano de Normas Tecnicas, Carrera 37 No. 52-95, P.O. Box 14237, Bogota

Costa Rica: Instituto Centroamericano de Investigaciones y Technologia Industrial, 4a Calle y Avenida la Reforma, Zona 10, Guatemala City, Guatemala

Cyprus: Ministry of Commerce and Industry of the Republic of Cyprus, Nicosia

Czechoslovakia: CSN, ON, Urad pro normalizaci a mereni, Vaclavske namesti 19, 11347 Praha 1

Denmark: DS, DS, Dansk Standardiseringsraad, Aurehojvej 12, DK-2900 Hellerup

Ecuador: INEN, Instituto Ecuatoriano de Normalizacion, Casilla 3999, Av. Universitaria 784, Quito

Egypt: EOS, Egyptian Organization for Standardization, 2 Latin America Street, Garden City, Cairo

El Salvador: Instituto Centroamericano de Investigaciones y Tecnologia Industrial, 4a Calle y Avenida la Reforma, Zona 10, Guatemala City, Guatemala

Ethiopia: ESI, Ethiopian Standards Institution, P.O. Box 2310, Addis Ababa

Finland: SFS, SFS, Suomen Standardisoimisliitto, P.O. Box 205, SF-00121 Helsinki 12

France: AFNOR, NF, Association Francaise de Normalisation, Tour Europe, Cedex 7, 92080 Paris-La Defense

Germany: DNA, DIN, Deutsches Institut fur Normung, Burggrafenstrasse 4-7, Postfach 1107, 1 Berlin 30

Ghana: GSB, Ghana Standards Board, P.O. Box M. 245, Accra

Greece: NHS, Hellenic Republic, Ministry of Industry, Standardization Division, 80 Mr. Iakopoulou Street, Athens

Guatemala: ICAITI, Instituto Centroamericano de Investigaciones y Tecnologia Industrial, 4a Calle y Avenida la Reforma, Zona 10, Apartado Postal 1552, Guatemala City

Honduras: Instituto Centroamericano de Investigaciones y Tecnologia Industrial, 4a Calle y Avenida la Reforma, Zona 10, Guatemala City, Guatemala

Hong Kong: Hong Kong Standards and Testing Centre, Eldex Industrial Bldg., 12th Floor, Unit A, 21 Ma Tau Wei Road, Hung Hom, Kowloom

Hungary: MSZH, Magyar Szabvanyugyi Hivatal, Postafiok 24, 1450 Budapest 9

Iceland: Industrial Development Institute, Skipholt 37, Reykjavik

India: ISI, IS, Indian Standards Institution, Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110001

Indonesia: YDNI, NI, Yayasan Dana Normalisasi Indonesia, Jalan Braga 40 Atas, Bandung

Iran: ISIRI, ISIRI, Institute of Standards and Industrial Research of Iran, Ministry of Industries and Mines, P.O. Box 2937, Teheran

Iraq: IOS, Iraqi Organization for Standards, Planning Board, P.O. Box 11185, Baghdad

Ireland: IIRS, IS, Institute for Industrial Research and Standards, Glasnevin House, Ballymun Road, Dublin 9

Israel: SI, Standards Institution of Israel, 42 University Street, Tel Aviv 69977

Italy: UNI, UNI, Ente Nazionale Italiano di Unificazione, Piazza Armando Diaz 2, 1 20123 Milano

Ivory Coast: Bureau Ivoirien de Normalisation, Ministere du Plan, B.P. 649, Abidjan

Jamaica: JBS, Bureau of Standards, 6 Winchester Road, P.O. Box 113, Kingston 10

Japan: JISC, JIS, Japanese Industrial Standards Committee, Agency of Industrial Science and Technology, Ministry of International Trade and Industry, 1-3-1 Kasumigaseki Chiyodaku, Tokyo

Jordan: Directorate of Standards, Ministry of Industry and Trade, P.O. Box 2019, Amman

Kenya: Kenya Bureau of Standards, P.O. Box 10610, Nairobi

Korea: KBS, KS, Bureau of Standards, Industrial Advancement Administration, Youngdeungpo-ku, Seoul, Republic of Korea

Kuwait: KSS, Ministry of Commerce and Industry, Post Box No. 2944, Kuwait

Lebanon: LIBNOR, Institut Libanais de Normalisation, B.P. 195144, Beyrouth

Liberia: Ministry of Commerce, Industry and Transportation, Division of Standards, Monrovia

Libya: Standards and Specifications Section, Department of Industrial Organization, Ministry of Industry, Tripoli

Madagascar: Ministere des Mines, de l'Industrie, du Commerce et du Ravitaillement, Service du Conditionnement, B.P. 1316, Tananarive

Malawi: Malawi Bureau of Standards, P.O. Box 946, Blantyre

Malaysia: SIRIM, Standards and Industrial Research Institute of Malaysia, SIRIM Secretariat, P.O. Box 544, Kuala Lumpur

Malta: Department of Industry, 30 South Street, Valletta, Malta

Mexico: DGN, DGN, Direccion General de Normas, Av. Cuauhtemoc No. 80, Mexico 7, D.F.

Morocco: SNIMA, Service de Normalisation Industrielle Marocaine, Direction de l'Industrie, Ministere du Commerce, de l'Industrie, des Mines et de la Marine Marchande, Rabat

Netherlands: NNI, NEN, Nederlands Normalisatie-Instituut, Polakweg 5, Rijswijk

New Zealand: SANZ, Standards Association of New Zealand, Private Bag, Wellington

Nicaragua: Instituto Centroamericano de Investigaciones y Tecnologia Industrial, 4a Calle y Avenida la Reforma, Zona 10, Guatemala City, Guatemala

Nigeria: NSO, Federal Ministry of Industries, Nigerian Standards Organization, 11 Kofo Abayomi Road, Victoria Island, Lagos

Norway: NSF, NS, Norges Standardiseringsforbund, Haakon VII's gt. 2, N-Oslo 1

Pakistan: PSI, PS, Pakistan Standards Institution, 39 Garden Road, Saddar, Karachi-3

Panama: Instituto Centroamericano de Investigaciones y Tecnologia Industrial, 4a Calle y Avenida la Reforma, Zona 10, Guatemala City, Guatemala

Paraguay: INTECNOR, Instituto Nacional de Tecnologia y Normalizacion, Avda Artigas y Gral Roa Casilla de Correa 967, Asuncion

Peru: ITINTEC, Instituto de Investigacion Tecnologica, Industrial y de Normas Tecnicas, Av. Abancay No. 1176, Piso 2, Apartado No. 145, Lima 1

Philippine Islands: KP, Philippines Bureau of Standards, 6th Floor, Manufacturers Bldg., Plaza Sta. Cruz, P.O. Box 3719, Manila

Poland: PKNiM, Polski Komitet Normalizacji i Miar, Ul. Electoralna 2, 00-139 Warszawa

Portugal: IGPAI, NP, Reparticao de Normalizacao, Avenida de Berna 1, Lisboa-1

Republic of South Africa: SABS, SABS, South African Bureau of Standards, Private Bag X191, Pretoria 0001

Rhodesia: Standards Association of Central Africa, Coventry Road, Workington P.O. Box 2259, Salisbury 4

Romania: IRS, STAS, Institutul Roman de Standardizare, Casuta Postala 6214, Bucarest 1

Saudi Arabia: SASO, Saudi Arabian Standards Organization, Airport Street, P.O. Box 3437, Riyadh

Singapore: SISIR, Singapore Institute of Standards and Industrial Research, 179 River Valley Road, P.O. Box 2611, Singapore 6

Spain: IRANOR, Instituto Nacional de Racionalizacion y Normalizacion, Serrano 150, Madrid 6

Sri Lanka: BCS, Bureau of Ceylon Standards, 53 Dharmapala Mawatha, Colombo 3

Sudan: SSD, Standardization and Quality Control Department, Ministry of Industry and Mining, P.O. Box 2184, Khartoum

Sweden: SIS, Sveriges Standardiseringskommission, Box 3295, S-103 66 Stockholm

Switzerland: SNV, SNV, *Association Suisse de Normalisation, Kirchenweg 4, Postfach, 8032 Zurich

Syria: Industrial Testing and Research Centre, P.O. Box 845, Damascus

Thailand: TISI, Thai Industrial Standards Institute, Depart-

ment of Science, Ministry of Industry, Rama VI, Bangkok 4

Trinidad: Trinidad and Tobago Bureau of Standards, Room 318, Salvatori Bldg., Frederick Street, P.O. Box 288, Port of Spain

Tunisia: Ministere de l'Economie Nationale, 195 rue de la Kasbah, Tunis

Turkey: TSE, TS, Turk Standardiari Enstitusu, Necatibey Caddesi 112, Bakanliklar, Ankara

United Kingdom: BSI, BS, British Standards Institution, 2 Park Street, London W1A 2BS, England

Uruguay: UNIT, UNIT, Instituto Uruguayo de Normas Tecnicas, Agraciada 1464, Piso 9, Montevideo

USSR: GOST, GOST, Gosudarstvennyj Komitet Standartov, Mer i Izmeritel 'nyh Priborov pri, 38 Kvartal Jugo-Zapada, Lorpus 189-a, Moska V-421

Venezuela: COVENIN, Comision Venezolana de Normas Industriales, Av. Boyaca (Cota Mil), Edf. Fundacion La Salle, Piso 5, Caracas 105

Yugoslavia: JZS, JUS, Jugoslovenski zavod za Standardizaciju, Cara Urosa ul. 54, Post pregr. 933, 11001 Beograd

Zambia: ZSI, Zambia Standards Institute, P.O. Box RW 259, Lusaka Lusaka

*Standards bearing other designations have also been approved by this Standards body.

APPENDIX 2

THE MEDICAL DEVICE COMMITTEES OF ISO

THE MEDICAL DEVICE COMMITTEES OF ISO

ISO/TC	42.	Photography radiographic film
ISO/TC	75.	Stretchers
ISO/TC	76.	Transfusion equipment for medical use
ISO/TC	84.	Syringes for medical use and needles for injections
ISO/TC	106.	Dentistry
ISO/TC	121.	Anaesthetic equipment and medical breathing machines
ISO/TC	136.	Furniture-Hospital furniture
ISO/TC	150.	Surgical Implants
ISO/TC	157.	Mechanical Contraceptives
ISO/TC	159.	Ergonomics
ISO/TC	168.	Prosthetics and orthotics
ISO/TC	170.	Surgical intruments
ISO/TC	172.	Optics and optical instruments
ISO/TC	173.	Technical aids for disabled and handicapped persons.

APPENDIX 3[1]

THE LIST OF TSE STANDARDS RELATED TO BIOMEDICAL EQUIPMENTS AND SUPPLIES UNTIL 1984 IN TURKEY

TSE STANDARDS			HEALTH
No	Approval Date	The Name of Standard	Price(TL)
1. Instruments for Surgery			
TS 3497	October 1980	Steril Suture	60
TS 3548	January 1981	* Surgical scissors	315
TS 3549	January 1981	* Surgical clamps	405
TS 3833	December 1982	Surgical gloves	105
TS 3946	March 1983	Surgical forcepts	-
TS 3948	March 1983	Wound retractor	-
2. Instruments used in medicine and their analyse methods			
a. The Instruments			
TS 3521	December 1980	Syringes for Medicine	80
TS 3592	March 1981	Needles for syringes	105
TS 3808	September 1982	Hot water bags	60
TS 3809	September 1982	Unvulcanized rubber ice bags	60
TS 3876	December 1982	Cotton swab	60
TS 3888	February 1983	Infusion carriers-mobile	-
TS 3944	March 1983	Tongue depressor	-
TS 3957	April 1983	Plasters	
TS 3971	April 1983	Plastic syringes, disposable steril	-
b. Analyse methods			
TS 3402	April 1979	The color code of medical gases	30

HEALTH

No	Approval Date		The Name of Standard	Price(TL)
3. Materials used in densitry				
TS 3591	March 1981	*	Tooth pulling instruments	135
TS 3733	April 1982		Mirrors for denstistry	75
TS 3753	April 1982		Elevators for surgery	75
TS 3922	March 1983		Tooth paste	
4. Glassware and experiment methods				
a. Glassware				
TS 3400	April 1979		Experiment tubes	75
TS 3401	April 1979		Glass petri dishes	75
TS 3507	November 1980		Microscope slides	45
TS 3760	April 1982		Graduated pipettes	120
TS 3761	April 1982		Sedimentation pipette	75
TS 3781	May 1982		Measuring graded cylinders	120
TS 3822	November 1982		Centrifuge tubes	75
b.Experiment methods				
TS 3399	April 1979		Properties of glassware tubing and joints	30
TS 3587	March 1981		Experiment for resistance of glass to acid (6N) at 100°C hydrochloric acid	45

Note:

* Mandatory standard.

APPENDIX 4[1]

TOPICS FOR HEALTH PREPARATORY GROUP OF TSE IN 1985-1986

HEALTH PREPARATORY GROUP

1. Topics from 1984 - 1985 Work Program:

A. New Topics

1. pH meter
2. Autoclave
3. Sterilizer
4. Aspirator tubing
5. Jaw spreader
6. Blood and serum bags and sets
7. Dry air sterilizer
8. Steam sterilizer
9. Wheel chair
10. Crutch
11. Body temperature
12. Blood and serum transmitter sets
13. Glass bulbs
14. Vaccination bottles
15. Porcelain capsule
16. Narrow-necked medication bottles
17. Plaster of Paris
18. Stretcher
19. Cathater

20. Vaginal diaphragm
21. Vaginal speculum
22. Gypsum cast bandage
23. Overbed tables
24. Dropping tube
25. Glass bulb tubes
26. Hair cream
27. Skin cream
28. Toilet powder
29. Hair paints
30. Plastic medicine measuring cups
31. The safety requirements for children toys mechanical and physical, chemistry properties and flammable
32. Contraceptive devices, general rules for uterus
33. Silk suture for surgery
34. Finger cot
35. Bandage with viskon
36. Bandage with nylon
37. Pharmaceutic box
38. Artificial seeding box
39. Baby cots
40. The experiments for the surgical metallic material
41. Silikat filling materials
42. Amalgam filling materials
43. Akrilik teeth
44. Zinc phospat
45. Mercury
46. Hydrolic physicon chair
47. Ambudevice

48. Sphygmomanometer

49. X-ray hand-wash tank

50. Aliminium eye ointment tube

51.Metal pharmaceutic holders

52.Plastic pharmaceutic holders

53. Plastic eye dropping tube bottles

54. Cosmetic cotton

55. Hygenic napkins

56. Surgical light

57. Surgical light

58. Cologne

58. Deodorant

59. Experiment methods for microbiologic cosmetics.

2. Topics in 1985-1986 Work Program

A. New Topics

1. Surgical table

2. Gynecologic examination table

3. E.N.T chair

4. Electrical centrifuge

5. Trommel

6. Stethescope

7. Bougie sets

8. Curette system

9. Patient examination table

10.Disposable blood-vessel cannula

11.Tarcheostomy cannula

12.Needles for dentistry

13. Humidifiers
14. Modification Carts
15. Air permeability for plastic pharmaceutical covers
16. Tuberculine syringes
17. The control methods for safe cover systems
18. Wheel chair
19. Sputum containers
20. Vaccination transfer containers
21. Blood transfer containers
22. Antiseptic liquid soaps

APPENDIX 5

THE TECHNICAL COMMITTEES OF IEC

THE TECHNICAL COMMITTEES OF IEC

Nos.

1. Terminology
2. Rotating machinery
3. Graphical symbols
4. Hydraulic turbines
5. Steam turbines
7. Bare aluminium conductors
8. Standard voltages, current ratings and frequencies
9. Electric traction equipment
10. Fluids for electrotechnical applications
11. Recommendations for overhead lines
12. Radiocommunications
13. Electrical measuring equipment
14. Power transformers
15. Insulating materials
16. Terminal markings and other identifications
17. Switchear and controlgear
18. Electrical installations in ships
20. Electric cables
21. Secondary cells and batteries
22. Power electronics
23. Electrical accessories
25. Quantities and units, and their letter symbols
26. Electric welding
27. Industrial electroheating equipment
28. Insulation co-ordination
29. Electroacoustics
31. Electrical apparatus for explosive atmospheres
32. Fuses
33. Power capacitors
34. Lamps and related equipment
35. Primary cells and batteries
36. Insulators
37. Surge arresters
38. Instrument transformers
39. Electronic tubes
40. Capacitors and resistors for electronic equipment
41. Electrical relays
42. High-voltage testing techniques
43. Electric fans for household and similar purposes
44. Electrical equipment of industrial machines
45. Nuclear instrumentation
46. Cables wires and waveguides for telecommunication equipment
47. Semiconductor devices and integrated circuits

Nos.

48. Electromechanical components for electronic equipment
49. Piezoelectric devices for frequency control and selection
50. Environmental testing
51. Magnetic componets and ferrite materials
52. Printed circuits
55. Winding wires
56. Reliability and maintainability
57. Telecontrol, teleprotection and associated telecommunications for elective power systems
58. Methods of measurement of electrical properties of metallic materials
59. Performance of household electrical appliances
60. Recording
61. Safety of household and similar electrical appliances
62. Electrical equipment in medical practice
63. Insulation systems
64. Electrical installations of buildings
65. Industrial-process measurement and control
66. Electronic measuring equipment
68. Magnetic alloys and steels
69. Electric road vehicles and electric industrial trucks
70. Degrees of protection by enclosures
71. Electrical installations for outdoor sites under heavy conditions (including open-cast mines and quarries)
72. Automatic controls for household use
73. Short-circuit currents
74. Safety of data processing equipment and office machines
75. Classification of environmental conditions
76. Laser equipment
77. Electromagnetic compatibility between electrical equipment including networks
78. Tools for live-working
79. Alarm systems
80. Navigational instruments
81. Lighting protection
82. Solar photovoltaic energy systems
83. Information technology equipment

C.I.S.P.R.: International special committee on radio interference

APPENDIX 6

THE MEDICAL DEVICE COMMITTEES OF IEC

THE MEDICAL DEVICE COMMITTEES OF IEC

IEC	TC1	Terminology, Radiology and Radiological Physics, Electrobiology
IEC	SC 140	Small special power transformers, Safety transformers
IEC	SC 290	Ultrosonics, Hearing aids, Ultrasonic diagnostic equipment, Ultrasonic therapeutic equipment
IEC	SC 45B	Health physics instrumentation
IEC	TC 61	Safety of household electrical appliances Ultraviolet and infrared radiating appliances
IEC	TC 62	Electrical eqiupment in medical practice
IEC	SC 62 A	Common aspects of electrical equipment in medical practice
IEC	CS 62 B	X-ray equipment operating up to 400 kV and accessories
IEC	SC 62 C	High energy equipment and equipment for nuclear medicine
IEC	SC 62 D	Electromedical equipment
IEC	TC 64	Electrical installations of buildings Installations in medically used rooms

IEC TC 76	Laser equipment
IEC TC 77	Electromagnetic compatibility between electrical equipment including networks
IEC CISPR	International special committee on radio interference

APPENDIX 7

THE LIST OF IEC STANDARDS

THE LIST OF IEC STANDARDS PREPARED BY COMMITTEE:29

AND SUB-COMMITTEE: 29C

PUBLICATION

118-0(1983): Hearing aids

Part O : Measurement of electroacoustical charasteristics

118-1(1983): Hearing aids

Part 1: Hearing aids with induction pick-up coil input

118-2 (1983):Hearing aids

Part 2: Hearing aids with automatic gain control circuits

118-3(1983): Hearing aids

Part 3: Hearing aid equipment not entirely worn on the listener

118-4(1981): Methods of measurement of electro-acoustical characteristics of hearing aids.

118-5(1983): Hearing aids

Nipples for insert earphones

118-7(1983):Hearing aids

Measurement of the performance characteristics of hearing aids for quality inspection for delivery purpose

118.8(1983):Hearing aids

Measurement of the performance characteristics of hearing aids under stimulated in stu working conditions

118-11(1983):Hearing aids

Symbols and other markings on hearing aids and related equipment

126(1973) :IEC reference coupler for the measurement of hearing aids using earphones coupled to the ear by means of ear inserts

150(1963): Testing and calibration of ultrasonic therapeutic equipment

224(1966): Marking of control settings on hearing aids

90(1973): Dimensions of plugs for hearing aids

318 (1970) : An IEC artificial ear, of the wide band type for the calibration of earphones used in audiometry

645 (1979): Audiometers

THE IEC STANDARDS PREPARED BY SUB-COMMITTEES:

62 A, 62 B, 62 C, 62 D

601-1(1977): Safety of medical electrical equipment
Part 1: General requirements

601-2(1981): Safety of medical electrical equipments
Part 2:Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV
Section one: General
Section two: Radiation safety for equipment

601-2.2(1982):Medical electrical equipment
Part 2: Particular requirement for the safety of high frequency surgical equipment

601-2.3(1982):Medical electrical equipment
Part 2: Particular requirement for the safety of short-wave therapy equipment

336(1982): Characteristics of focal spots in diagnostic X-ray tube assemblies for medical use

407(1973): Radiation protection in medical X-ray equipment 10 kV to 400kV

522(1976): Inherent filtration of an X-ray tube assembly

572(1977): Determination of the luminance distrubition of electro-optical X-ray image intensifiers

406(1975):Radiographic cassettes

407(1975):Equipment for dental radiology

526(1978):High voltage cable plug and socket connections for medical X-ray equipment

731(1982):Medical electrical equipment
Dosimeters fith ionization chambers as used in radiotherapy

613(1978):Electrical, thermal and loading characteristictics of rotating anode X-ray tubes for medical diagnosis

520(1975):Entrance field sizes of electro-optical X-ray image intensifiers

536(1976): Classification of electrical and electronic equipment with regard protection against electric shock

658(1979):Radiographic intensifying screens for medical use , Dimensisons

580(1977): An exposure product meter

573(1977):Measurement of the conversion factor of electro-optical X-ray image intensifiers

637(1979):Making of and accompanying documents for X-ray tubes and X-ray tube assemblies for medical use

627(1978):Characteristics of anti-scatter grids used in X-ray equipment

479(1974): Effect of current passing through the human body-Technical Committee:64

C.I.S.P.R

(11,11A,1975): Limits and methods of measurement of radio interference characteristics of industrial scientific and medical radio-frequency equipment

APPENDIX 8

ABBREVIATIONS AND ADRESSES

RELATED TO STANDARDS ORGANIZATIONS

AAMI : The Association for the Advancement of Medical Instrumentation.

AAMI, 1901 N. Ft. Myer Dr., Suite 602, Arlington VA 22209 (703) 525-4890

ACHIG : The American Conference of Governmental Industrial Hygienists.

ADA : American Dental Association

ANSI The American National Standards Institute ANSI, 1430 Broodway, New York, NY 10018 also has an office in Europe : ANSI, 16 Chem de la Voie Creuse, 1211 Geneva, Switzerland.

ASTM : American Society for Testing and Materials

ASHE American Society for Hospital Engineering 840 North Lake Shore Drive Chicago, Illionis 60611

DHSS Department of Health and Social Sucurity 14 Russell Square, London WC1B 5EP

EDMA European Diagnostic Manufacturers Association

EUCOMED: European Confederation of Medical Suppliers Association - London

FDA : Food and Drug Administration

GATT : General Agreements on Tariffs and Trade

IEC : International Electrotechnical Commission Central office of the IEC
1. Rue de Varembe / GENE/ A - Switzerland Sales Department of the Central Office, of the IEC, 3, rue de Varembe, 1211 Geneva 20
Telex : 22872 CEIEC - CH
Telephone : (022) 340150

ISO : International Organization for Standardization
1. Rue de Varembé
1211 Geneva 20 - Switzerland

JCAH : Joint Commission of the Accreditation of Hospitals

MDSB : Medical Device Standard Board (of ANSI)

NBS : National Bereau of Standards

NCCLS : National Committe on Clinical Laboratory Standards

NFPA : National Fire Protection Association
NFPA - Batterymarch Park, Quincy, MA 02269

OSHA : The Occupational Safety and Health Administration

TSE : Turkish Standards Institution

Necatibey Cad. No:112 / Bakanlıklar - ANKARA

Telex : 42047 TSE-TR Tel : 187240/18

TSE - İst. Bölge Müdürlüğü

Meşrutiyet Cad. 162 / Beyoğlu-İST.

Tel : 143 32 02

TSE - İzmir Bölge Müdürlüğü

Tel : 21 48 10

Kültür Mah. Şehit Nevres Bulvarı 7/5 - İzmir

APPENDIX 9

THE COLOR CODE OF MEDICAL GASES

ISO-32-1977(E)

THE COLOR CODE: MEDICAL GASES

"Gas Cylinders for Medical Use-Marking for Idenfication of Content" ISO 32-1977(E), lists white as the cotor for oxygen.

Medical gases come in cylindrical tanks that are color coded to denote the contents. Oxygen may come in tanks of seven different colors, depending on the country. Consider:

Green: Columbia, Ecuador, Mexico, Thailand, Uruguay, United States, Venezuela, West Indies

Gray: Luxembourg

Black: Japan

Blue and White: Brazil, Denmark

Blue: Austria, Holland, Switzerland, West Germany

White Soulder: Australia, United Kingdom (w/Blackbody)

White: Argentine, Belgium, Canada, Finland, France, Greece, Hong Kong, Ireland, India, Italy, Kenya, Malaysia, New Zeland, Nigeria, Norway, Pakistan, Portugal, Rhodesia, Singapore, South Africa, Spain, Sweeden

APPENDIX 10

AN EXAMPLE OF AN IEC STANDARD:

IEC-62-D

Draft- Medical Electrical Equipment

Part 2:Electroconvulsive therapy equipment

particular requirements for safety

Not for reproduction
Original: English

62D (Secretariat) 36
January 1985

INTERNATIONAL ELECTROTECHNICAL COMMISSION

TECHNICAL COMMITTEE No. 62: ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE

SUB-COMMITTEE 62D: ELECTRO-MEDICAL EQUIPMENT

Draft - Medical electrical equipment.
Part 2: Electroconvulsive therapy equipment
particular requirements for safety

Preface

This Particular Standard amends and supplements IEC Publication 601-1 (first edition 1977), Safety of Medical Electrical Equipment, Part 1: General Requirements, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

The title of the General Standard will be changed in the next edition to read:

> Medical Electrical Equipment,
> Part 1: General Requirements for Safety.

This change is anticipated in the title of this Particular Standard.

The numbering of sections, clauses and sub-clauses of this Particular Standard corresponds with that of the General Standard. Sub-clauses or figures which are additional to those of the General Standard are numbered starting from 101; additional Appendices are lettered AA, BB etc., and additional items aa), bb) etc.

The requirements are followed by specifications for the relevant tests.

Terms defined in clause 2 of the General Standard or of this Particular Standard are written in CAPITALS

llowing the decision taken by Sub-Committee 62D at the meeting
Washington in 1979, a rationale for the more important re-
irements is given in Appendix AA.

is considered that a knowledge of the reasons for these requi-
ments will not only facilitate the proper application of the
andard but will, in due course expedite any revision necessitated
changes in clinical practices or as a result of developments in
chnology. However, this Appendix does not form part of the re-
irements of this standard.

is draft is based on document 62D-WG 2 (UK) 1, distributed in
2, taking into account the written and oral comments thereon
the results of the discussion on the WG 2 meeting in Erlangen
October, 1982.

D R A F T

MEDICAL ELECTRICAL EQUIPMENT. PART 2 : ELECTROCONVULSIVE THERAPY EQUIPMENT PARTICULAR REQUIREMENTS FOR SAFETY

Section one - General

1. Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard specifies the requirements for ELECTRO-CONVULSIVE THERAPY EQUIPMENT, hereinafter referred to as ECT EQUIPMENT or EQUIPMENT, as defined in sub-clause 2.1.22.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Addition:

The ECT electrodes and all parts conductively connected to them.

Additional definitions:

2.1.22 ELECTROCONVULSIVE THERAPY EQUIPMENT

EQUIPMENT including accessories for the application of electrical energy via electrodes in direct contact with the head of a PATIENT for the treatment of certain psychiatric disorders.

2.1.23 OUTPUT WAVEFORM

The variations in magnitude of an electrical signal (in either voltage or current) as a function of time appearing across the ECT electrodes.

2.1.24 STIMULUS

Current (voltage) of a certain OUTPUT WAVEFORM delivered by the EQUIPMENT electrodes for a preselected time.

2.1.25 STANDBY

A mode of operation in which the EQUIPMENT is operational, but the APPLIED PART is not energized.

3. General requirements

This clause of the General Standard applies.

4. General requirements for tests

This clause of the General Standard applies except as follows:

.1 Item b)
ddition in item b):
dditional routine tests: see Appendix B

. Classification
his clause of the General Standard applies except as follows:

.1 Amendment:
elete CLASS III EQUIPMENT.

.2 Amendment:
elete TYPE B EQUIPMENT.

. Identification, marking and documents
his clause of the General Standard applies except as follows:

.1 Item j). Power input, lines 39 to 41

eplacement
he RATED power input of MAINS OPERATED EQUIPMENT shall be the aximum power input averaged over any period of 2s.

.8 ACCOMPANYING DOCUMENTS

.8.2 Instructions for Use
dditional item:
s) The instructions for use shall additionally contain:

. Advice on the preparation of the PATIENT including the use of conductive gel or liquid to provide for effective electrode - scalp coupling without bridging the electrodes by this conductive medium.

. A description of the correct method of handling the EQUIPMENT electrodes.

. A warning to the user not to touch the conductive parts of the electrodes during treatment.

. Advice to avoid stimulating over or near to a defect in the skull.

. Advice on precautions in the use of any monitoring systems irrespective whether or not these are part of the EQUIPMENT.

. A recommendation calling the USER's attention to the need for periodic maintenance of the EQUIPMENT especially:

a) inspection of cables and electrodes and their handles for defects.

b) cleaning and storage of electrodes after use, in particular those electrodes fitted with control switches.

c) a functional check.

7. Information on the OUTPUT WAVEFORM, maximum amplitude of the output voltage and/or current and the effect of load resistance on these parameters.

6.8.3 Technical description
Additional item:
aa) The technical description shall additionally give full details of the OUTPUT WAVEFORM when the EQUIPMENT is connected in turn to resistive loads of 200Ω, 300Ω and 500Ω.

7. Power input
This clause of the General Standard applies except as follows:

7.3 Additional item
aa) The power input shall be measured with a load resistance having a value within the range specified in the technical description (see 6.8.3) and with the output and any accessible timer controls set to maximum.

Section Two - Safety Requirements
Clauses 8 to 11 of the General Standard apply.

12. SINGLE FAULT CONDITION
This clause of the General Standard applies except as follows:
Addition:
- any defect which results in the output circuit becoming LIVE (see Sub-clause 51.102)

Section Three - Protection against Electric Shock Hazards
Clause 13 of the General Standard applies.

14. Requirements related to classification
This clause of the General Standard applies except as follows:

14.3 Not applicable.

14.4 Item a)
Amendment:
Delete CLASS III EQUIPMENT and Figure 4.

14.6 Replacement

ECT EQUIPMENT shall be TYPE BF or CF EQUIPMENT.

Clauses 15 to 18 of the General Standard apply.

19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS
This clause of the General Standard applies except as follows:

19.1 Item b) line 33
Replacement
In the STANDBY condition, including the charging of any energy storage device and
during the delivery of a STIMULUS (except PATIENT AUXILIARY CURRENT).
19.1 Item e)
Replacement:
The PATIENT LEAKAGE CURRENT shall be measured with the output unloaded from each electrode to earth, the following parts being connected together and to earth:

1. ACCESSIBLE CONDUCTIVE PARTS

2. metal foil on which the EQUIPMENT is positioned and which has an area at least equal to that of the base of the EQUIPMENT.

3. any SIGNAL INPUT PARTS and SIGNAL OUTPUT which may be connected to earth in NORMAL USE.

19.1 Item f)
Addition:
The PATIENT AUXILIARY CURRENT shall only be measured with the EQUIPMENT operating in the STANDBY condition.

19.2 Item b), lines 7 to 16

Not applicable.

19.2 Item b), lines 17 and 18:
Replacement
- a voltage equal to 110% of the highest RATED MAINS VOLTAGE applied between earth and the ECT ELECTRODES connected together, metal foil being wrapped around and in intimate contact with, the electrode handles and connected to earth and to the parts 1 to 3 of sub-clause 19.1 e) of this Particular Standard, the EQUIPMENT being disconnected from the SUPPLY MAINS and the MAINS PART connected to earth.

20. Dielectric strength
This clause of the General Standard applies except as follows:

20.2 B-b Not applicable.

20.2, last paragraph

Addition:
The electrical insulation of parts B-f shall not be investigated if the PATIENT LEAKAGE CURRENT and ENCLOSURE LEAKAGE CURRENT are not higher than the allowable limit for NORMAL CONDITION if a short circuit between relevant parts of the EQUIPMENT is made.

20.3 Values of test voltages
Amendment:
The test voltages for insulations B-a and B-f shall be 4 U or 6 kV, fo insulations B-d shall be 2 U or 3 kV, whichever is the higher, all reference and test voltages being in terms of peak voltage.

20.4 Tests
Additional item:
aa) The insulation of the ECT electrodes shall be able to withstand a dielectric strength test performed with a test voltage as specified in sub-clause 20.3 above for insulations B-d between the conductive surfaces of the electrodes and non-conductive parts likely to be handled in NORMAL USE.

Compliance shall be checked by application of the combined test of sub-clause 44.6 of this Particular Standard.

Section Four - Protection against Mechanical Hazards
Clause 21 to 28 of the General Standard apply.

Section Five - Protection against Hazards from Unwanted or Excessive Radiations
Clause 29 to 36 of the General Standard apply.

Section Six - Protection against the Hazards of Explosions in Medically used Rooms
Clause 37 to 41 of the General Standard apply.

Section Seven - Protection against Excessive Temperatures, Fire and other Hazards, such as Human Errors

42. Excessive Temperatures
This clause of the General Standard applies except as follows:

42.4, Item 3) Duty cycle
Replacement:
The EQUIPMENT shall be operated in the STANDBY mode until temperature equilibrium is attained. Then the EQUIPMENT is operated into a resistive load of 500 Ohms with any controls set to give maximum output 60 times at a rate of one STIMULUS per 2 min. The temperature limits specified in clause 42 of the General Standard shall not be exceeded.

Clause 43 of the General Standard applies.

44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

This clause of the General Standard applies except as follows:

44.3 Spillage

Replacement:

The EQUIPMENT shall be so constructed that, in the event of spillage of liquids (accidental wetting), no safety hazard shall result.

Compliance shall be checked by the following tests:

The EQUIPMENT shall be placed in the position of NORMAL USE.

It is then subjected for 30 s to an artifical rainfall of 5 mm/min falling vertically from a hight of 0,5 m above the top of the EQUIPMENT. (For the details of the test apparatus see Figure 35 of the General Standard).

An intercepting device may be used to determine the duration of the test.

Immediately after the 30 s exposure, visible moisture on the BODY OF THE EQUIPMENT shall be removed.

Immediately after the above test, inspection shall show that any water which has entered the EQUIPMENT cannot adversely affect the safety of the EQUIPMENT. In particular, the EQUIPMENT shall be capable of meeting the requirements of this Standard.

44.6 Ingress of Liquids

Additional item

The electrode handles shall be protected against ingress of liquids.

Compliance shall be checked by the following test:

The electrode assembly is completely immersed for period of 24 h in water the conductivity of which has been increased by the addition of a small quantity of salt. After this preconditioning treatment moisture is first removed from the insulating surface for a distance of approximately 10 mm from the conductive surface of the electrode. The electrode assembly is then re-immersed in the water except that the conductive parts of the electrode are maintained well above the surface. A test voltage having a value as specified in sub-clause 20.4 aa) of this Standard is applied between the water and the conductive parts of the electrode, the electrode cable may be used for this purpose.

45. Pressure vessels and parts subject to pressure

This clause of the General Standard applies.

46. Human errors

This clause of the General Standard applies except as follows:

Additional sub-clauses

46.101 The EQUIPMENT shall be so designed that operation into open circuited or short circuited electrodes does not impair the ability of the EQUIPMENT to comply with the requirements of this Standard.

Compliance shall be checked by the following test:
With any accessible controls set to give maximum STIMULUS output the EQUIPMENT is operated at a rate of one STIMULUS per minute 10 times in the open circuited condition and 5 times in the short circuited condition. After this test the EQUIPMENT shall comply with all the requirements of this Standard.

46.102 Release switch
The means for triggering the STIMULUS shall be so arranged that accidental energization of the electrodes is minimized. When hand held electrodes are provided the switch shall be located in one of the electrode handles. The switch may be located on the control panel of the EQUIPMENT where the electrode assembly incorporates other means for its retention on the head of the PATIENT. A foot operated switch shall not be used. The switch shall not require continuous activation during the delivery of the STIMULUS.

Compliance shall be checked by inspection and functional test.

Clauses 47 and 48 of the General Standard apply.

49. Interruption of the power supply
This clause of the General Standard applies except as follows:

49.2 Replacement:
When the EQUIPMENT is switched off and on again or the SUPPLY MAINS is interrupted and re-established.

a) the output amplitude shall not deviate by more than 10 % from the preset value

b) the output duration shall not deviate by more than 10 % from the preset value

c) there shall be no unintended output.

Compliance shall be checked by the following test:
With the EQUIPMENT operating in the NORMAL CONDITION the amplitude and duration of the output is measured. The power supply to the EQUIPMENT is interrupted and restored after 1 s, the switch on the EQUIPMENT being left in the ON position. Measurement of the amplitude and duration of the output is repeated and compared with the previous measurements.

The test is repeated by operating the mains switch of the EQUIPMENT, while the SUPPLY MAINS is not interrupted.

Changes in the output values shall not exceed those specified.

Additional sub-clause

49.101 In case of a failure of the SUPPLY MAINS or of an INTERNAL ELECTRICAL POWER SOURCE or the mains switch being switched off the APPLIED PART shall not be energized.

Compliance shall be checked by a functional test.

Section Eight - Accuracy of the Operating Data and Protection against Incorrect Output

50. Accuracy of operating data
This clause of the General Standard applies except as follows:

50.2 Replacement:
The measured maximum output energy shall not deviate from the figures given in the ACCOMPANYING DOCUMENTS by more than ± 30% for the load resistances specified in sub-clause 6.8.3. The measured peak amplitude, pulse duration and STIMULUS duration shall not deviate by more than ± 15 %.

Compliance shall be checked by measurement.

51. Protection against Incorrect Output
This clause of the General Standard applies except as follows:

51.2 Limitation of output values
Replacement
The output energy shall be limited to a maximum of 100 Joules at 500Ω for each treatment initiation. Within that energy limit the output voltage shall be limited to a peak level of 1 kV and the current to a peak level of 2 A at any load resistance, excluding transients having a duration of less than 50 µs.

Compliance shall be checked by measurement of peak voltage and current and by measurement or calculation of the energy.

Additional sub-clauses

51.101 Supply voltage fluctuations
Supply voltage fluctuations of ± 10 % shall not affect the EQUIPMENT output amplitude by more then 10 %.

Compliance shall be checked by measurement at a single resistive load within the range specified in Sub-clause 6.8.3.

51.102 Output indicator
An audible indication shall be provided whenever the output circuit is energized under NORMAL CONDITIONS or SINGLE FAULT CONDITIONS. The indication shall be present throughout the period of energization. The audible indication shall not exceed 65 dB (A) at a distance of 1 m from the EQUIPMENT and it shall not be possible to reduce the sound level below 45 dB (A) by any control accessible to the USER. The sound output shall have its major energy content in the band of frequencies between 100 and 1000Hz. If additionally a visual indication is provided it shall be coloured yellow.

Compliance shall be checked by inspection and the following test: With the microphone of a sound level meter complying at least with Type 3 requirements of IEC 651 positioned 1 m from the EQUIPMENT the sound level is measured with any sound level control set to its maximum and minimum values. The measured sound level at thes two values shall be as specified.

51.103 OUTPUT WAVEFORM
The pulse duration shall not exceed 50 % of the pulse period; the pulse duration shall be between 1 ms and 5 ms and the pulse repetition frequency shall be between 50 Hz and 150 Hz, when the output is loaded with 300 Ohms.

Compliance shall be checked by inspection and measurement.

51.104 Output timer
The EQUIPMENT shall be provided with a timing device which de-energizes the output after a pre-selected period. It shall be adjustable by the USER to give a STIMULUS duration not exceeding 10s with an error not exceeding $\pm$ 15%.

Compliance shall be checked by inspection and measurement.

Section Nine - Fault Conditions causing Overheating and/or Mechanical Damage; Environment Tests
Clauses 52 and 53 of the General Standard apply.

Section Ten - Constructional Requirements
Clause 54 to 55 of the General Standard apply.

56. Components and general assembly
This clause of the General Standard applies except as follows:

Additional sub-clause
56.101 ECT Electrodes
a) Electrodes shall be so designed as to minimize the possibility of contact between the electrodes and the operator in NORMAL USE. The electrode handles shall be made of insulating material and shall have no ACCESSIBLE CONDUCTIVE PARTS.

Compliance shall be checked by inspection and performing the dielectric strength test required by sub-clause 44.6 of this Particular Standard.

b) The electrode cables shall be detachable from the EQUIPMENT by means of a connector.

Compliance shall be checked by inspection.

c) The minimum area of the conductive surface of each of the electrodes shall be 20 cm^2.

Compliance shall be checked by measurement.

57. MAINS PARTS, components and layout

This clause of the Genral Standard applies except as follows:

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

Additional item

aa) Between the LIVE PARTS of an electrode and parts of the electrode handle likely to be touched in NORMAL USE there shall be a CREEPAGE DISTANCE of at least 20 mm and an AIR CLEARANCE of at least 10 mm.

Compliance shall be checked by measurement.

Clauses 58 and 59 of the General Standard apply.

Appendix AA: Rationale

Replacement
This Appendix provides a concise rationale for the important requirements of the standard and is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore as clinical practice and technology change it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

Introduction
The output of ECT EQUIPMENT (voltages of several hundred volts and currents in excess of 1A) is potentially hazardous to both PATIENT and operator if the EQUIPMENT is not properly designed and constructed. The requirements of this Standard are deemed to be the minimum necessary to provide for an adequate degree of safety while allowing the maximum freedom for design and construction of the EQUIPMENT. It is pointed out that these requirements are not intended to be applied to EQUIPMENT produced prior to the publication of this Standard.

AA 1.1 Scope
The scope of this Particular Standard does not include EQUIPMENT for electro-analgesia, electro-sleep and similar applications.

AA 2.1.25 STANDBY (definition)
For EQUIPMENT incorporating a storage capacitor for the STIMULUS energy the STANDBY mode includes charging of this capacitor.

AA 5. Classification
AA 5.1 According to the definition of CLASS III EQUIPMENT in the General Standard, the safety of CLASS III EQUIPMENT relies on its supply. As the supply circuit is not in the scope of this Standard such EQUIPMENT had to be excluded. Furthermore voltages exceeding the limit of MSELV are needed for ECT.

AA 5.2 The APPLIED PART must be isolated in order to reduce hazards to the USER and to exclude unwanted current paths through the PATIENT. Bothe, PATIENT and USER may have a conductive connection to earth and significant capacitance to earth.

AA 6. Identification, marking and documents
AA 6.1 j) Power input
EQUIPMENT incorporating an energy storage device may have an increased power input during its charging period. The USER should operate the EQUIPMENT on a suitably rated mains circuit.

6.8.2 Item ac)
1. Effective electrode-scalp coupling is essential to produce a seizure and to reduce the risk of skin burns.

4. The skull provides a relatively high resistance to the flow of current through the PATIENT'S head. Skull defects near the electrodes will cause current concentrations.

6. This maintenance is regarded to be important for the safety of PATIENT and USER.

6.8.3 Item aa)
As the PATIENT resistance is subject to variation details of the WAVEFORM and the effect of changes in load resistance should be made available to the USER.
14. Requirements related to classification
14.3 CLASS III EQUIPMENT
See rationale on sub-clause 5.1.

14.6 TYPES B, BF and CF EQUIPMENT
See rationale on sub-clause 5.2.

19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS
These requirements provide for a sufficient degree of isolation of the APPLIED PART. Clearly, during the delivery of a STIMULUS the PATIENT AUXILIARY CURRENT cannot be measured.
19.2 b)
Even under the SINGLE FAULT CONDITION of a PATIENT having a connection to the supply mains the PATIENT shall not be in danger while the electrodes are applied to his head.

20. Dielectric strength

20.2 B-f: Only an insulation preventing excessive LEAKAGE CURRENTS needs to be tested.

20.3 The test voltages specified are considered to be adequate having in mind in view of the relatively short period for which the output is energized.

20.4 Item aa) Adequate insulation of the electrode handle is essential for the safety of the USER. The use of conductive coupling agents has been taken into account.
42. Excessive temperatures
42.4 Item 3) Duty cycle
The test conditions specified are deemed to represent the most severe operation of ECT EQUIPMENT likely to occur in clinical use.

AA 44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

AA 44.3 Spillage
This requirement takes into account the possibility of spillage of conductive liquids in NORMAL USE.

AA 44.6 Ingress of liquids
Unsuitable design of the electrodes is known to be a cause of electric shock to the operator. Adequate insulation of the electrode assembly is therefore required. The use of conductive gels and liquids may result in bridging of protective insulation or of switches which trigger the STIMULUS unless the ingress of such gels or liquids is prevented by an adequate construction.

AA 46. Human errors

AA 46.101 Triggering the STIMULUS with open or short circuited electrodes is considered to be misuse. Nevertheless it may occur in practical use and hence the EQUIPMENT shall be able to withstand a limited number of such operations.

AA 46.102 This requirement does not exclude the use of two switches, one in each of the hand held electrode handles. A switch requiring continuous activation could, if inadvertently released by the operator during the STIMULUS, result in the delivery of energy to the PATIENT but without the production of a seizure. In an emergency the operator may interrupt the treatment by retracting the electrodes. If an electrode retaining device is used, the electrode connector may be removed (56.101 b) or the equipment may be switched off. A foot operated switch is considered to be potentially hazardous because of the risk of inadvertent operation.

AA 49. Interruption of the power supply

AA 49.2 Interruption and restoration of the mains shall not cause a significant change in the output parameters nor cause unintented triggering of a STIMULUS.

AA 49.101 Any internally stored energy must not energize the electrodes after the interruption of the supply (externally or by means of the switch).

AA 50. Accuracy of operating data

AA 50.2 For safety reasons the output delivered by the EQUIPMENT should correspond within acceptable limits with the values declared by the manufacturer as excessive energies may cause damage to the brain and insufficient output will be ineffective to produce the seizure. The tolerances specified are deemed adequate in view of the lack of general medical agreement on the electrical output necessary.

51. Protection against incorrect output

51.2 Limitation of output values
The specified energy limit is considered adequate to produce effective seizure when waveforms according to the requirements of sub-clause 51.103 are used. Limits for the peak values for voltage and current are specified in order to reduce the possibility of injury to the PATIENT, the risk of electric shock to the USER, and damage to other EQUIPMENT which may be connected to the PATIENT. This applies especially to the peak voltage of EQUIPMENT of the constant-current type.

51.101 Supply voltage fluctuations
Supply voltage fluctuations within the limits of the General Standard must not unduly affect the output amplitude.

51.102 Output indicator
The USER is watching the PATIENT during treatment, therefore a visual indication is inadequate. As the presence of an unintended voltage on the electrodes due to a fault in the EQUIPMENT cannot be excluded, the indication is required for this type of SINGLE FAULT CONDITION.

51.103 OUTPUT WAVEFORM
The requirements are specified so as to minimize the amount of energy required to produce a seizure. Though unmodified sinewaves have been widely used for many years it would appear that this has been a matter of convenience in the design of very simple types of EQUIPMENT. However it is known that the use of unmodified sinewaves requires considerably higher energies for producing a seizure than other types of waveforms, for example relatively short rectangular pulses. The limits for pulse duration allow for a variety of pulse forms, e.g. rectangular, modified sinewaves. The use of pulse durations significantly outside the specified limits can result in a seizure, but with the use of excessive energy.

51.104 Output timer
Since the applied energy is directly proportional to STIMULUS duration, a timer is a necessary requirement for PATIENT safety. The requirement allows for the adjustment of STIMULUS duration with an adequate degree of reproducibility.

56. Components and general assembly
56.101 ECT electrodes
a) These requirements are aimed for safety of the operator.
b) Detachable electrode cables make cleaning and disinfection procedures of the electrodes easier.
c) Excessive current densities under very small electrodes would cause skin burns.

57. MAINS PARTS
57.10 Item aa) Components and layout
Relatively large distances are required to allow for the probable spread of conductive gel or liquid.

Appendix A of the General Standard does not apply.

Appendix B

Testing During Manufacture and/or Installation

Additional routine tests:

Using a load resistance of 300Ω in every produced item of ECT EQUIPMENT the following output characteristics should be tested:

1. Waveform

2. Amplitude

3. STIMULUS duration

Appendices C to J of the General Standard apply.

Appendix K of the General Standard does not apply.

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APPENDIX 11

COLLECTIVE STANDARD ON GRAPHICAL SYMBOLS FOR ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE IEC-62A (Draft)

Original : Bilingue
Bilingual

62A(Secrétariat)52
62A(Secretariat)52

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMITE D'ETUDES N° 62:
EQUIPEMENTS ELECTRIQUES DANS LA PRATIQUE MEDICALE

SOUS-COMITE 62A:
ASPECTS GENERAUX DES EQUIPEMENTS ELECTRIQUES UTILISES EN PRATIQUE MEDICALE

TECHNICAL COMMITTEE N° 62:
ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE

SUB-COMMITTEE 62A:
COMMON ASPECTS OF ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE

P R O J E T

NORME REPERTOIRE DES SYMBOLES GRAPHIQUES POUR EQUIPEMENTS ELECTRIQUES EN PRATIQUE MEDICALE

D R A F T

COLLECTIVE STANDARD ON GRAPHICAL SYMBOLS FOR ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE

Introduction

Le présent projet a pour but d'établir, en vue d'une consultation commode, la liste des symboles graphiques pour équipements électro-médicaux, sur lesquels un accord s'est déjà manifesté au sein du groupe de travail 5 : "Symboles" du SC62A et du Sous-Comité 3C "Symboles graphiques utilisés sur les appareils", après prise en considération des commentaires internationaux sur les projets antérieures 62A (Secrétariat) 33, 62A (Secrétariat) 42, et, le cas échéant, des demandes des autres Groupes de travail du CE 62.

Le présent projet présente séparément les symboles provenant de la Publication CEI 417 ou de l'ISO, en donnant leur numéro de référence correspondant.

Les symboles fondamentaux pour la conformité aux normes élaborées par le CE62 ou ses Sous-Comités sont également répertoriés. Ces symboles ne sont pas encore approuvés par le SC3C.

Un grand nombre de symboles figurant dans ce document sont utilisés sur les appareils depuis de nombreuses années, et sont donc bien connus des experts spécialistes dans ce domaine; la signification des autres symboles s'éclairera en se plaçant dans le contexte de l'appareil lui-même; mais il faut reconnaître

Introduction

The intention of this draft is to list for easy reference those graphical symbols on medical electrical equipment about which agreement has already been reached within SC62A-WG5 'Symbols' and SC 3C 'Graphical symbols for use on equipment' after considering international comments on the previous drafts 62A (Secretariat) 33, 62A (Secretariat) 42 and the requirements of other Working Groups within TC 62, where known.

This draft lists separately those symbols already published by the IEC in Publication 417 or by ISO. A reference to the relevant symbol number is given.

Those symbols essential for compliance with the standards issued by TC 62 or its Sub-Committees are also listed. These symbols are not yet approved by IEC-SC 3C.

Many of the symbols listed here have already been used for many years on equipment and will be familiar to experts in that particular field, the meaning of others may become clear when viewed in context on the equipment itself, but it must be appreciated that it is impossible to

qu'on ne parviendra pas à rendre immédiatement évidente la signification de tous les symboles figurant sur un équipement complexe. A noter toutefois que, pour tous les symboles figurant sur un appareil, cette signification doit être donnée dans les documents d'accompagnement de l'appareil.

make self-evident the meaning of all symbols on complex equipment. However it is noted that the meaning of all symbols used on equipment shall be explained in the accompanying documents to the equipment.

Les symboles catalogués dans le présent document sont destinés à être placés sur le matériel utilisé en pratique médicale; ils ne sont pas nécessairement associés aux symboles graphiques utilisés sur les dessins ou schémas.

The symbols, listed in this document, are intended to be displayed on equipment used in medical practice. They are not necessarily associated with graphical symbols used on drawings.

Pour les besoins en symboles non satisfaits par la présente liste, il convient dans un premier stade, de se reporter aux symboles publiés par la CEI ou par l'ISO. Il faut aussi noter que, si nécessaire, plusieurs symboles ou éléments de symboles peuvent être regroupés pour revêtir une signification particulière, et dans la mesure où le caractère évocateur principal du symbole est conservé, une certaine latitude dans la réalisation graphique est admise.

For symbol requirements not met by this list refer in the first instance to published IEC or ISO symbols. Note that where necessary, two or more symbols or symbol elements may be grouped together to convey a particular meaning and provided that the essential communicative characteristics of the basic symbol are maintained some latitude in graphic design is permissible.

Les symboles sont regroupés par sections pour des raisons de commodité de recherche. Une table alphabétique est en préparation et sera ajoutée lors de la publication finale du document.

The symbols are grouped together in sections for easy access. An alphabetical index is in preparation and will be added to the final publication of the document.

Lors de la réunion du SC62A tenue à Paris en mars 1979, il a été décidé de rassembler 62A(Secrétariat)33 et 62A (Secrétariat)42 en un seul document pour diffusion sous la Procédure Accélérée.
En application de cette décision, le présent projet est diffusé à tous les Comités Nationaux sous la Procédure Accélérée définie au paragraphe 6.1.2. des Directives Générales pour les travaux de la CEI.
Si, à l'issue d'un délai de trois mois après la diffusion de ce projet, un appui suffisant s'est exprimé en faveur de sa soumission pour approbation suivant la règle des Six mois, un avis officiel sera diffusé avec les bulletins de vote pour que les Comités Nationaux expriment leurs votes officiels suivant la Règle des Six mois.

At the meeting of SC62A in Paris, March 1979 it was decided to combine 62A(Secretariat)33 and 62A(Secretariat)42 in one document to be circulated under the Accelerated Procedure.
According to this decision this draft is circulated to all National Committees under the Accelerated Procedure as laid down in Sub-clause 6.1.2 of the General Directives for the work of the IEC.

If within three months after the circulation of this draft, sufficient support has been expressed in favour of considering it as submitted for approval under the Six Months' Rule, a formal notice will be circulated, together with voting papers for National Committees to record their formal votes under the Six Months' Rule.

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Marche-arrêt (bouton poussoir)
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qu'indiqué par le symbole No. 1)

Arrêt (interne, variante de "arrêt(mise hors tension)" tel
qu'indiqué par le symbole No. 2)

Attente, ou veille (interne: en association avec les
symboles 6 et 7)

Démarrage (d'une opération)
Arrêt (mise hors service)
Pause; interruption momentanée
Commutateur à touche à deux fonctions, stable dans chaque
position, pos."en"

Commutateur à touche à deux fonctions, stable dans chaque
position, pos."hors"

Courant alternatif
Courant alternatif triphasé
Courant alternatif triphasé avec neutre
Courant continu
Courant continu et alternatif
Borne de terre de protection
Borne de terre générale, y inclus fonctionnelle
Borne anti-parasitée (sans bruit)
Masse, chassis
Point ou borne d'égalisation des potentiels
Variabilité
Idem 24, mais à un nombre des positions discrètes
Idem 24, pour commandes par rotation
Idem 26, mais à un nombre des positions discrètes
Polarité positive
Moins; polarité négative
Point de référence ou étalonnage
Lampe; éclairage; illumination
Eclairage indirect (pour postes de commande)
Eclairage de la salle à basse intensité,
par exemple pour éclairage rouge d'accomodation

Température
Baisse de la température (température décroissante)
Hausse de la température (température croissante)
Entrée
Sortie
Commande à distance
Commande locale
Ouverture
Fermeture
Voyant de signalisation
Mise à zéro sur appareils de mesure et d'affichage
Mise en position centrale
Commutateur à main
Fonctionnement à commande manuelle
Commande automatique
Verrouiller (verrouillé)(Embrayage (enclenchement mécanique))
Déverrouiller (déverrouillé) (Débrayage (déclenchement mécanique))
Fixer ou bloquer
Libérer (Débloquer, desserrer)
Déplacement dans un sens
Déplacement dans les deux sens
Mouvement de et vers l'opérateur
Mouvement dans le sens de la flèche, vers un arrêt prédéterminé
Mouvement rectiligne limité)

Mouvement en deux ou plusieurs étapes
Mouvement dans le sens de la flèche à partir d'une position
pré-établie

Mouvement semi-circulaire (à partir d'une position pré-établie)
Mouvement suivant un arc
Vitesse normale dans le sens de la flèche (en combinaison avec 62)
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position fixe (en combinaison avec 63)
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Mouvement rapide dans le sens de la flèche vers une position fixe
(combination avec 65)

Ventilateur (Général)
Fermeture (de nature mécanique)
Fermé (de nature mécanique)
Ouverture (de nature mécanique)
Ouvert, (de nature mécanique)
Réglage de l'ouverture d'un diaphragme à iris
Commutateur à pédale

Section 1
General Symbols

NUMERICAL INDEX

1 On (power)
2 Off (power)
3 Stand-by
4 On/off (push-push)
5 On/off (push-button)
6 On (internal: other than "On (power)" as indicated by Symbol Nr. 1)
7 Off (internal: other than "off (power)" as indicated by Symbol Nr. 2)
8 Stand-by (internal: in association with Symbols 6 and 7)
9 Start (of action)
10 Stop (of action)
11 Pause; interruption
12 Two-function push-switch, stable in each position, "in"-position
13 Two-function push-switch, stable in each position, "out"-position
14 Alternating current
15 Three phase alternating current
16 Three phase alternating current with neutral conductor
17 Direct current
18 Both direct and alternating current
19 Protective earth (ground) terminal
20 General earth terminal, including functional
21 Noiseless (clean) earth (ground)
22 Frame or chassis
23 Equipotential point or terminal
24 Variability
25 As in 24, with a number of discrete positions
26 As in 24 for rotating controls
27 As in 26, with a number of discrete positions
28 Positive polarity, increase
29 Minus; negative polarity, decrease
30 Reference point or calibration
31 Lamp; lighting; illumination
32 Indirect lighting (for control panels etc.)
33 Low intensity room lighting e.g. red accomodation lighting
34 Temperature
35 To reduce temperature (temperature falling)
36 To raise temperature (temperature rising)
37 Input
38 Output
39 Remote control
40 Local control
41 Timer
42 Bell
43 Signal light
44 Zero setting on instruments and display units
45 Setting to central position
46 Hand-held switch
47 Manual operation
48 Automatic control
49 To lock (locked)(Engaging (mechanical enable))
50 To unlock (unlocked)(Disengaging (mechanical disable))
51 Tighten or lock, at random (mechanical or electrical)
52 To release, unlock, unclamp, at random (mechanical or electrical)
53 Movement in one direction
54 Movement in both directions
55 Movement to and from the operator
56 Movement in direction of arrow to a predetermined stop (limited linear motion)
57 Movement in two or more steps
58 Movement in direction of arrow from a pre-set position
59 U-turn of movement
60 Arcuate movement
61 Normal speed in direction of arrow (in combination with 62)
62 Fast speed in direction of arrow (in combination with 61)
63 Movement with normal speed in direction of arrow from a fixed position (in combination with 64)
64 Movement with fast speed in direction of arrow from a fixed position (in combination with 63)
65 Movement with normal speed in direction of arrow to a fixed position (in combination with 66)
66 Movement with fast speed in direction of arrow to a fixed position (in combination with 65)
67 Ventilator (General)
68 To close (mechanical)
69 Closed, (mechanical)
70 To open, (mechanical)
71 Opened, (mechanical)
72 Iris diaphragm aperture adjustment
73 Foot switch

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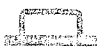
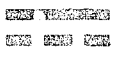
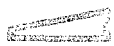
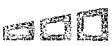
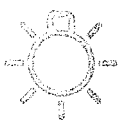
9  IEC 417-5104	10  IEC 417-5110	11  IEC 417-5111	12 	13 	14  IEC 417-5032	15  IEC 335-1	16  IEC 601-1
17  IEC 417-5031	18  IEC 417-5033	19  IEC 417-5019	20  IEC 601-1	21  IEC 417-5018	22  IEC 417-5020	23  IEC 417-5021	24  IEC 417-5004
25 	26 	27 	28  IEC 417-5005	29 IEC 417-5006	30 	31  IEC 417-5012	32 
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1 Matériel de Classe II
2 Appareil médicale de type B
3 Protection contre les chocs de defibrillation appareil de type B
4 Appareil médical de type BF
5 Protection contre les chocs de defibrillation appareil de type BF
6 Appareil médicale de type CF
7 Protection contre les chocs de defibrillation appareil de type CF
8 Protégé contre les chutes d'eau verticales
9 Protégé contre les projections d'eau
10 Etanche à l'eau
11 Appareils catégorie AP
12 Appareils catégorie APG

Section 2
Type indentifying, for marking the type or class of equipment

NUMERICAL INDEX

1 Class II equipment
2 Type B medical equipment
3 Defibrillator proof, type B equipment
4 Type BF equipment
5 Defibrillator proof, type BF equipment
6 Type CF equipment
7 Defibrillator proof, type CF equipment
8 Drip-proof
9 Splash-proof
10 Watertight
11 Category AP equipment
12 Category APG equipment

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ection 3
vertissement

NDEX NUMÉRIQUE

Haute tension
Attention! Consulter les documents d'accompagnement
Advertisement: rayonnement ionisant

Pour identifier la borne de terre pour le conducteur supplémentaire de protection voir CEI Publ 601-1, 19.3

Rayonnements non ionisant
Condition de défaut

Point de raccordement du conducteur pour le neutre sur un appareil installé de façon permanente

Section 3
Safety signs

NUMERICAL INDEX

1 High voltage
2 Attention! Consult accompanying documents
3 Warning: Ionizing radiation

4 To identify the terminal for the additional protective earth conductor. For application see IEC Publ. 601-1, sub-clause 19.3

5 Non-ionizing radiation
6 Fault condition

7 Connection point for the neutral conductor on permanently installed equipment

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nisants

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Radiographie (général)
Radiographie indirecte (par photo); le format du film) peut être indiqué

Radioscopie
Foyer fin ou ultra fin
Petit foyer
Gros foyer
Tube à rayons X; Grille pouvant être ajouté, si prescrite
Source rayons X en train de rayonner
Gaine radiogène équipée
Technique exposition isolée
Expositions en série
Expositions en radio-cinéma
Statif vertical de radioscopie
Statif vertical de radiographie
Table horizontale de radiographie
Statif de radiophotographie
Caméra de radiophotographie
Tomographe horizontal (général)
Table basculante avec tube au-dessous
Table basculante avec tube en-dessous
Compresseur inutilisé, en position escamotée
Mouvement du compresseur dans le sens de la flèche
Compresseur (en position de fonctionnement)
Compression (sous pression)
Grille mobile
Grille fixe
Sans grille
Fin de d'exposition par dispositif de mesure du rayonnement (les champs choisis peuvent être indiqués)

Diviseur sériographe (dispositif pour découpes ou division du film)
Choix du format et de l'orientation du film, cliché unique (la dimension nominal du film peut être indiquée)

Comme 30
Comme 30, avec division, comme indiqué
Comme 30, avec division, comme indiqué, la dimension nominale du
Comme 30, avec division, comme indiqué, la dimension nominal du film peut être indiquée

Changeur de film, ou de cassette (fonctionnement uni-directionnel)
Comme 34 (fonctionnement bidirectionnel)
Fonctionnement bidirectionnel simultané
Fonctionnement bidirectionnel alterné
Colonne porte-tube à appui au sol
Equipement porte-tube plafonnier
Table d'urologie
Table chirurgicale
Chaise de patient; rotation autour d'un axe vertical
Chaise de patient; rotation autour d'un axe horizontal
Crâniographe (générale)
Arceaux (support semi-circulaire)
Bras en U (support à branches parallèles)
Mammographie
Poste de commande (commutation depuis le poste de commande)
Amplificateur de luminance (général)
Entrée stabilisée pour radioscopie avec amplificateur de luminance
Amplificateur de luminance (image de dimension normale)
Amplificateur de luminance (image agrandie)
Amplificateur de luminance: getter (dégazage)
Filtre de rayonnement
Seringue d'injection
Centreur lumineux
Champ lumineux (diaphragme à champ lumineux)
Dispositif de limitation du faisceau (ouvert)
Dispositif de limitation du faisceau (fermé)
Commande séparée des jeux de volets dans un dispositif de limitation du faisceau; ouverture du jeu de volets indiquée par les traits épais (ou ouvert)

Commande séparée des jeux de volets dans un dispositif de limitation du faisceau; fermeture du jeu de volets indiquée par les traits épais (ou fermé)

Patient mince en combinaison avec 63 et 64
Patient normal en combinaison avec 62 et 64
Patient épais en combinaison avec 62 et 63
Basculement de la table dans le sens indiqué
Mouvement du plan de table ou du marchepied dans le sens indiqué
Déplacement progressif du plan de table, dans le sens indiqué
Mouvement du plan de table dans le sens de la flèche
Mouvement dans le plan de la table
Mouvement du plan de table ou du marchepied, dans le sens indiqué
Mouvement du berceau dans le sens indiqué
Mouvement du plan de table autour d'un axe, comme indiqué
Mouvement du tomographe vers la position de départ
Mouvement tomographique d'essai (à blanc, voir 76)
Tomographie, cliché tomographique
Choix du plan de coupe tomographique dans le sens de la flèche
Vitesse normale de rotation de l'anode
Vitesse rapide de rotation de l'anode

Section 4
Specialized, for ionizing radiation equipment

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1 Radiography (exposure general)
2 Indirect radiography; the format size may be indicated
3 Radioscopy (Fluoroscopy)
4 Fine or ultra fine focal spot
5 Small focal spot
6 Large focal spot
7 X-ray tube; Grid may be added, if required
8 X-ray source emmiting
9 X-ray tube assembly
10 Single exposure technique
11 Serial exposure
12 Cine radiographic exposure
13 Vertical fluoroscopic stand
14 Vertical radiographic stand
15 Horizontal radiographic table
16 Photo-fluorographic stand
17 Photo-fluorographic camera
18 Horizontal tomograph (general)
19 Tilting table with over table tube
20 Tilting table with under table tube
21 Without compression device (parked)
22 Movement of compressor in direction of arrow
23 Compression device (in position for use)
24 Compression (compression is applied)
25 Moving grid
26 Fixed grid
27 Without grid
28 Termination of exposure by radiation measurement (selected fields may be indicated, the field format as appropriate)

29 Serial changer (spot film device)
30 Film format and orientation selection, single exposure (nominal film size may be indicated)

31 As 30
32 As 30, sub-division as indicated
33 As 30, sub-division as indicated, nominal film size may be indicated
34 Film or cassette changer (single plane operation)
35 As 34 (bi-plane operation)
36 Simultaneous bi-plane operation
37 Alternating bi-plane operation
38 Floor tube stand
39 Ceiling tube support
40 Urological table
41 Surgical table
42 Patient's chair; rotation about a vertical axis
43 Patient's chair; tilt about a horizontal axis
44 Skull unit (general)
45 C-arm
46 U-arm
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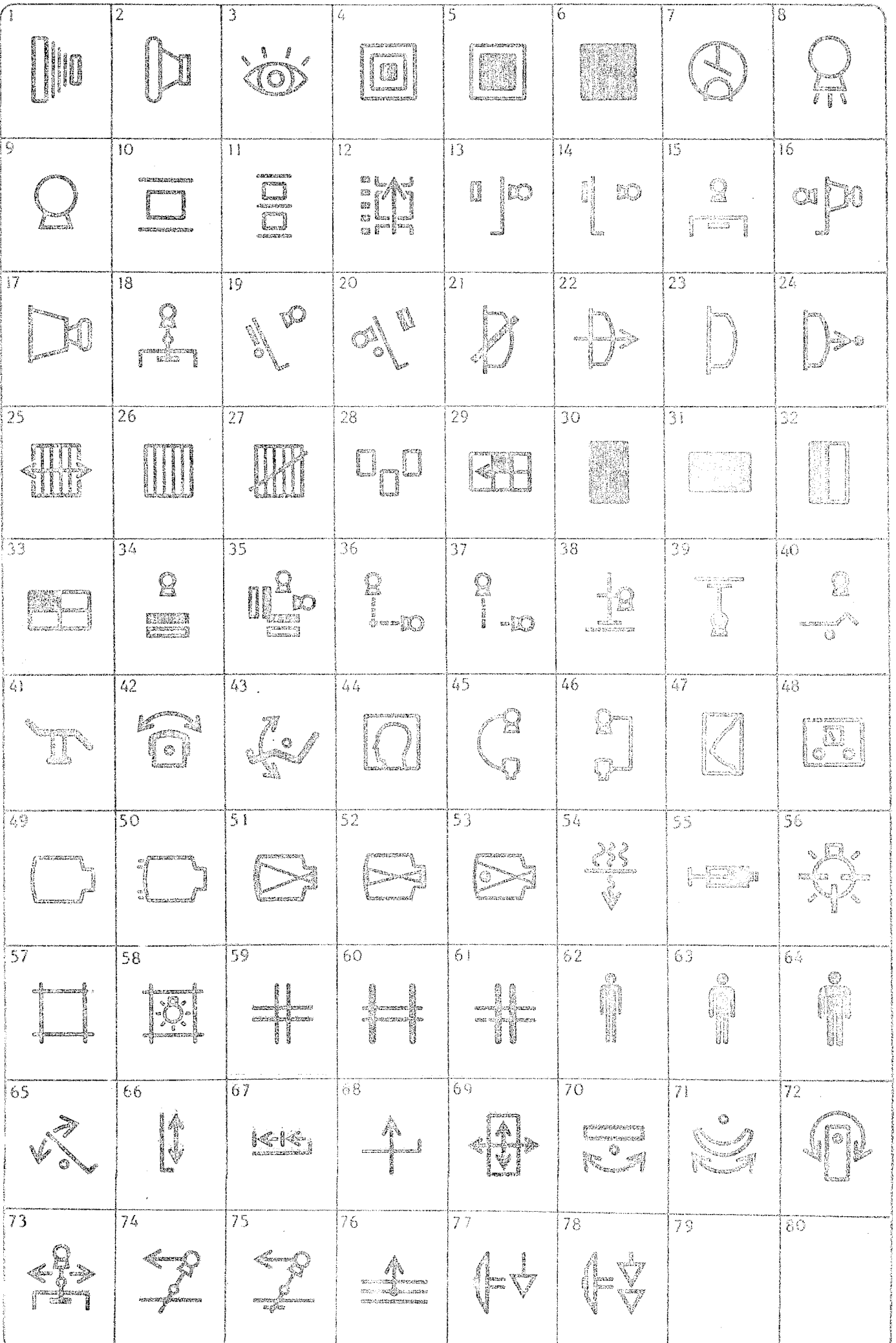
50 Stabilized input for image intensifier fluoroscopy
51 Image intensifier (normal size image)
52 Image intensifier (enlarged image)
53 Image intensifier, getter
54 Radiation filter
55 Injection syringe
56 Centring device using light beams
57 Field illumination (light-beam diaphragm)
58 Beam limiting device (open)
59 Beam limiting device (shut)
60 To open sets of shutters, as indicated by thick lines, in beam limiting device (or opened)

61 To close sets of shutters, as indicated by thick lines, in beam limiting device (or closed)

62 Patient, thin in conjunction with 63 and 64
63 Patient, normal in conjunction with 62 and 64
64 Patient, obese in conjunction with 62 and 63
65 Tilting of table in direction indicated
66 Table top or foot rest movement in the direction as indicated by arrow(s)

67 Table top incremental shift, in direction indicated
68 Table top movement in direction of arrow
69 Movement in plane of table top (use arrows as appropriate)
70 Table top or foot rest movement in direction indicated
71 Cradle movement in direction indicated
72 Movement of table top about axis as shown
73 Movement of tomograph to starting position
74 Tomography, test movement (see 76)
75 Tomography, tomographic exposure
76 Tomographic layer selection in direction of arrow
77 Normal speed anode rotation
78 High-speed anode rotation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Section 5
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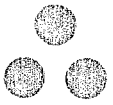
	10 	11 	12  IEC 417-5057	13  IEC 417-5056	14  IEC 417-5048	15 	16 
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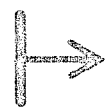
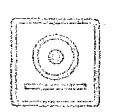
	26  IEC 417-5164	27 	28  IEC 417-5170	29  IEC 417-5165	30 	31 	32 
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Section 7
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