Norsk Klassifisering
Koding & Nomenklatur
Norwegian Nomenclature

The Evolution of the Norwegian Classification System for Medical Equipment

Bøe, Fields, Larsen, Randa

MEDISINSK TEKNISK FORENING

Norwegian Society for Biomedical Engineering

Thanks to the energies generated by the clinical engineers of Norway this work has been made possible—and it is a fitting afterthought to dedicate our thanks, and this book, to their society, the Norwegian Society for Biomedical Engineering.

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The work of the NKKN has, despite their late entry upon the international scene of coding, classification and nomenclature design, become more and more readily recognised for its integrity, quality and resolution.

This book is yet another carefully contemplated measure made towards reaching the foremost goals targeted by NKKN, namely, the establishment of a Common European Nomenclature and Coding System for Medical Devices developed along the lines and beliefs of the NKKN.

Some of the issues targeted in this book:

- The required structure for a new classification system.
- The establishment of a common European database system for medical devices.
- Nomenclature Design—guidelines and pitfalls.
- Terminology control.
- Device labelling and coding—the present and the future.
- Categorising Medical Devices.
- The pros and cons of equipment registration.

Europe, through the application of the Medical Device Directives, and its powers to enforce regulatory requirements, has now a unique opportunity to build a coding and classification system of sufficient high quality to support the requirements of all "players" in the single market. The chance is now at hand, either to create yet another system of haberdashery that most likely will cast a multitude of users into an endless quagmire of further frustration—or get to grips with the simple, yet extremely complicated, job of connecting the abstract to the tangible.

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Norwegian Nomenclature

The Evolution of the

Norwegian Classification System

for

Medical Equipment

"We must set down the subject itself, its definitions and all its properties"
Aristotle (384-322 BC)

Det Hvite Huset
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All the members of the NKKN project steering committee and the expert groups.

Medisinsk Teknisk Forening (Norwegian Society for Biomedical Engineering) for the economic support that enabled us to publish this book, and for sharing and supporting our views and visions.

Preface

This book is the result of many years of hard; often uncompromising work, that has through time involved many people in the simple, menial task of the systematisation of medical equipment. A chore long since accomplished in our everyday society where we do not even bother our heads with a second thought about the bar-coding on the chocolate wrapper as we discard it into the nearest litter bin, or the massive coding and computing task behind the unfavourable bank statement we received last week in the post.

Indeed, the following chapters are the culmination of great amounts of expended energies that has prompted the authors to take a stand off view of their ongoing efforts, inciting them to record their works, such as they stand today.

After a somewhat, but not uncommon, heated debate, the word *evolution* was timidly introduced into the title, for it can be justly proclaimed—to be an evolution that was disclosed, and not just a process or happening.

Thinking back, to the early days of when an inventory list seemed like a good idea and perhaps a handy thing to have around, it seems incredulous that any further development of the Mesozoic aged systems we and others struggled with, could have taken place at all.

And had it not been for that one singular day, when the tolerance level of Terje lost all conception, and he himself exploded into a fit of absolute exasperation over the complete absurdity of the then imposed national coding and classification system, it is probable that the change of things to come, would have been lost into obscurity.

"*Til helsikens med all dritten, vi lager en kode sjøl!*", were his "famous (but not) last words" in native tongue (ought not to be translated), and promoted the start of the new era, where Arne, Alan, Jan and many others to whom we owe endeared gratitude, took up the sword and smote at the many ugly heads of the Hydra.

We all owe a very special thanks to Mr. *Jacob W. Nordan*, for his unshakable belief, confidence and support in this project and our efforts, and without his visionary intuition in recognising a viable project, none of this would have been possible.

This book, which actually began its infantile days as the concluding report to the NKKN project's steering committee, is mainly concerned with the design and implementation of a Classification System for Medical Devices. It became apparent however, that such an accumulation of research, knowledge and experience should be put to better use. We are at all times carefully considering that this nomenclature and classification system might be implemented for the other device categories, or integrated/merged with existing or new classifications for these. We anticipate that the following pages will greatly contribute to the extensive work of constructing a European data exchange system for healthcare products. We by no means acclaim to provide all the answers to the multitude of questions that arise, but certainly believe that many constructive debates will be sparked to life and hopefully help all of us to find the best solutions for posterity. We might, in fact, be looking at the incubation of a new type of profession where the art of mobilising great quantities of information into databases will be managed by a new breed of professionals.

Haukeland University Hospital (HUH)

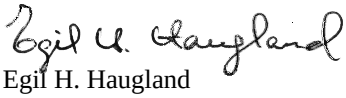
The Haukeland University Hospital is one of the five regional hospitals serving Norway's population of 4.2 million. Being located in the city of Bergen it covers the Western region which includes the counties of Rogaland, Hordaland and Sogn og Fjordane, which is known as Region 3, or Region West in the National Health plan. The hospital was established in the centre of Bergen in 1794, and moved to its present location in 1912. HUH achieved its status as Norway's largest regional hospital and university clinic in 1983 with the opening of the new Central Block. In addition to the normal hospital functions, it hosts a wide variety of specialities along with some national functions such as the highly specialised Burns Unit, Hypobar Unit and a radiation knife for treatment of brain tumours. With a great diversity in both professions, treatment, diagnostic methods, research, modern medical equipment and facilities, the hospital frequently produces results of international renown.

Some of the key figures are:

- Total building area of approximately 250,000 sq. meters. The main building, the Central Block, has alone a gross floor area of 125,000 sq. meters.
- Number of beds are approximately 1100.
- 50.000/180.000 in-patients/outpatients are diagnosed and treated yearly.
- Number of employees in 1993 was 5000 full-time or part-time employed, of which approximately 4000 have permanent jobs.
- 120 medical students per year.
- Total running costs in 1993 was NOK 1480 mill. (ECU 176 mill.).
- The value of the Medical Equipment (approx. 7000 registered devices) is valued at NOK 500 mill. (ECU 60 mill.). This is the purchase value void of appreciation adjustments).

The hospital boasts a self contained Technical Department of 100 employees which along with its reserve of supplies can remain operative for six months regardless of whatever crisis.

The Clinical Engineering Department is an independent unit and has a staff of approximately 30 persons divisioned into five groups: Anaesthesia equipment, Electronics, Specialised Mechanics, X-ray equipment and Clinical directed activities (Audiology, Extra-Corporeal assistance, EEG-lab and MR-lab)—and the 6th., a semi-official group for Research and Development provides the NKKN project team with the opportunity to escape their daily duties in order to do the NKKN work.



Egil H. Haugland
Managing Director
Haukeland Sykehus
University Hospital

Medical Devices—the definition

The most recent definition of the term *Medical Device* originates from the Medical Devices Directive[1] (MDD) issued by the Council of the European Communities (CEC). This definition will serve as the umbrella term used for a number of more or less distinct device categories which has been (and still will be) used by different professions in the medical field. The definition reads as follows:

> "**Medical device** (hereinafter referred to as "device") means any instrument, apparatus, appliance, material or other article, including software required for its proper functioning, whether used alone or in combination, intended by the manufacturer to be used for human beings solely or principally for the purpose of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
> - investigation, replacement or modification of the anatomy or of a physiological process,
> - control of conception,
>
> and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means." [MDD Article 1 §2 (a)]

NB! The term *Medical Device* is in this book hereinafter referred to as *device*, though with some exceptions where the original term is used to avoid confusion.

Categories of Medical Devices

There exists different views of how to categorise devices, but a sensible approach would be to restrict the categories to no more than ten different divisions according to natural, professional and regulatory reasons. A proposal from the Norwegian Competent Authority divides the devices into the following seven categories:

1) Aids for handicapped and rehabilitation devices

2) Medical Equipment

3) Dental articles

4) Disinfectants

5) Glasses and contact lenses

6) In Vitro Diagnostics (IVD)

7) Single-use articles

   a) Implants
   b) Sterile
   c) Non-sterile

Some of the devices will inevitably fall into two or more of these Categories, e.g. an infusion pump can be found both in the categories *Medical Equipment* (*ME)* and *Aids for handicapped and rehabilitation devices*.

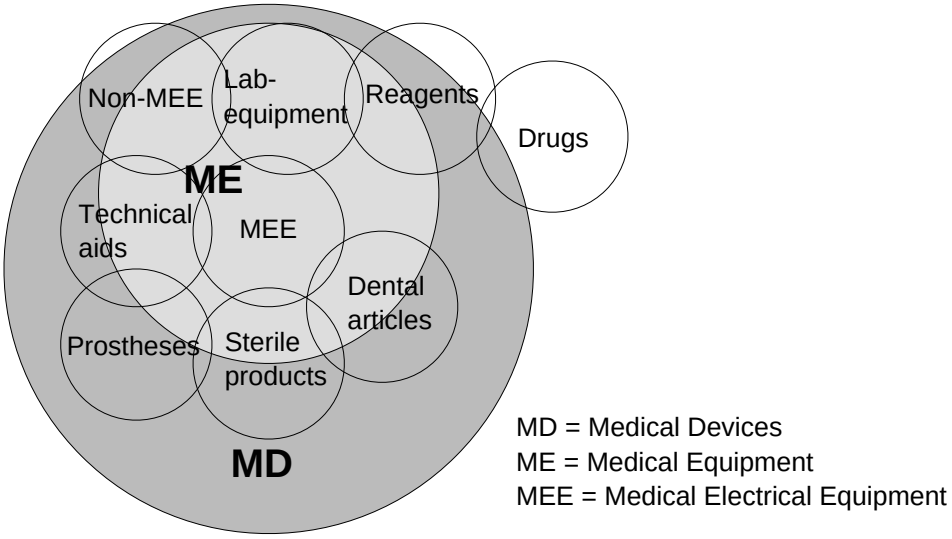


Figure 1: Examples of Device Categories covered by the umbrella term "Medical Devices".

The Norwegian Nomenclature (NKKN) project was mandated to make the nomenclature for all categories of Medical Devices. Since this is a massive task, and since the project originated from the clinical engineering profession, it was natural for us to start with the ME category. In the following paragraphs we have given a short description of each category according to the list starting on the previous page.

1) Aids for handicapped and rehabilitation devices

The majority of the equipment in this category is non-active ME such as; crutches, incontinence napkins, etc., but can also be active ME like infusion pumps and dialysis equipment for home use. This means that the category comprises equipment that also can be found in the category for ME.

2) Medical Equipment (ME)

Medical Equipment is an old and traditional term for all equipment and devices handled by the Clinical Engineering Departments (CED). It was defined in 1980 by the Ofstad Committee as follows:

"Medical Equipment is technical equipment constructed and/or marketed for use in the health care sector, and which does not concern the running of buildings".[2]

Another definition used is:

"All technical devices used for patient treatment, monitoring and diagnosis." [CED/HUH]

Medical Electrical Equipment (MEE)

This kind of equipment is a subset of the ME category, and covers ME powered by electricity (mains or battery). This subset is the same as the one covered by IEC 601-1[5]. Most of the Norwegian regulations for medical equipment applies to *Medical Electrical Equipment*. According to new Norwegian regulations, equipment for *In Vitro Diagnostic* (IVD) use, where the result of the test is used for patient diagnosis or treatment, are now included in this subset.[3]

All *MEE* can be categorised as *Active Medical Devices*, as defined by CEC.

Since most ME of today is powered by electricity, this definition only leaves some gas and mechanical equipment outside the subset.

3) Dental articles

This category includes both surgical instruments for dental treatment and materials such as amalgam alloys. Dental materials used in Norway are certified by the Scandinavian Institute of Dental Materials (NIOM), and are in compliance with international standards (ISO, EN) or NIOM's acceptance programs.

4) Disinfectants

All kinds of disinfectants are found in the category Disinfectants, both disinfectants for decontaminators, for instrument sterilising by immersion and for cutaneous use etc.

5) Glasses and contact lenses

This category includes contact lenses and glasses only. In Norway, the Department of Ophthalmology at HUH runs a register for events with these kind of products.

6) In Vitro Diagnostics

This category comprises all kind of IVD including reagents for laboratory use.

7) Single-use articles

There exists a great amount of devices (hundreds of thousands) that can be categorised as *Single-use articles*, and one has therefore found it reasonable to divide the category into three subdivisions:

a) Implants
b) Sterile
c) Non-sterile

a) Implants

Implants can be both active (e.g. pacemakers) and non-active (e.g. hip prostheses). The active implants are already covered by the category *Medical Equipment*, and it will therefore be necessary to cross-correlate these products to the mentioned category. Other implants, like bone prostheses, artificial teeth, artificial eyes, etc. will be covered by this category, but because of the fact that some of these are also regarded as sterile products, these will have to be cross-correlated to the subdivision *Sterile* (see below).

A national Norwegian register for hip prostheses is run by the Department of Orthopaedics at HUH. All hip prosthesis implant operations in Norway are recorded in this register.

b) Sterile

This category contains sterile products like catheters for urologic or invasive use, cannulas, infusion sets, syringe needles, mandrins, guidewires, tubes, electrodes for pacing, bandages, etc.

c) Non-sterile

The subdivision Non-sterile comprises products like disposable bags and packaging, paper towels, drapes, clothing, drinking beakers, etc.

Background

General

Since 1980, all health institutions in Norway have been obliged to keep an inventory containing MEE in order to comply with a regulation from Norwegian Authority for Energy and Water resources (NVE). The regulation states:

> "The owner of medical electrical equipment must keep a card file or other systematic inventory for the medical electrical equipment. From this file, the following information shall be available for each device:
>
> - Model, make, supplier and year of purchase
> - Accessories and supplementing equipment
> - Modifications, repairs and maintenance (what, when, by whom)
>
> There shall be an unambiguous agreement between the file and the different pieces of equipment." [NVE, FEB 1991 §810.3.4]

To accomplish this the smaller hospitals have usually kept their inventory in a manual card index, while the larger hospitals resorted to electronic database systems. The latest trend is, however, that even the smaller hospitals have transferred their inventory to electronic database systems that fulfil the above requirements, and which also adds even more functionality to serve the CED. Since the early attempts of making an inventory, predating the regulation mentioned above, a Norwegian version of the Danish DSI-nomenclature was used to classify the equipment. This nomenclature was coded using a significant numeric code, which in turn hindered future expansion. In addition, the chosen terms were often not in accordance with terms acceptable by clinical engineers.

The lack of a data model describing the relations between entities like equipment, Device Type, nomenclature and suppliers created much confusion among clinical engineers and system designers. Until recently, this has led to huge problems with the validity and quality of the data entered into the inventories. An illustrative example is that most systems allow the registration of the Device Type designation as free text. This has invariably resulted in, even within the same hospital, ambiguous registration of the same type of equipment, causing searches and reports to fail. At the same time, the same type of equipment might be related to different terms in the nomenclature causing even more confusion. Some examples of this are shown in table 1, 2 and 3:

Company name:
Philips
Phillips
Philips AS
Philips AS.
Philips Norge
Philips AS Norge

Table 1: Different and erratic spelling of a Company name.

Device Type:
Hewlett Packard 78342A
Hewlett Packard 78342 A
Hewlett-Packard 78342A
Hewlett Pakard 78342 A
H.P. 78342A
HP 78342A

Table 2: Different and erratic spellings of Makes and Model.

Defibrillator	**Defibrillator, battery powered**
S&W DMS600	Hewlett-Packard M1722B
S&W DMS600/3	S&W DMS600

Table 3: Confusion when relating Device Types to an ambiguous nomenclature.

Errors like this may not be so dramatic in a manual inventory, but in a computerised database system an exact match on the terms to be searched for is crucial, and is therefore an absolute requirement. For example, if defibrillators are related to different terms in the nomenclature, it would be difficult to retrieve simple information such as how many defibrillators the hospital possess. Perhaps some of the defibrillators are related to a newly created term, e.g. *Heart starters*, and since this term may be unknown to the person asking for a report, this would lead to erroneous results.

A real life example illustrating the validity of the above statement is shown in table 4, and it clearly illustrates how complete confusion can be created in a database system. The database, from which this table was collected, had a simple data model with only two entities, the individual Device and the Device Group (nomenclature), and with the type designation entered as free text within the Device entity. The hospitals CED staff managed to register, as a result of this, a number of devices with the same type designation: `Turbo-Puls T-P 1000` in eight different ways. When a search is made using these data, even

with a highly wildcarded search criteria, the computer will most likely find only one or a few matching data elements. This example is taken from a CED with only 2 - 3 clinical engineers, and is made available with the kind permission of *Mr. Svein Skutle*, manager of the CED at *Sentralsykehuset i Akershus*.

Code	Make	Model
2756	TURBO PULS	TP 1000
2750	TURBO PULS A/B	T-P 1000
2754	TURBO PULS SYST	TP 1000
2751	TURBO PULS SYST.	T-P 1000
2755	TURBO PULS SYST.	TP 1000
2753	TURBO PULS SYSTEM	TP 1000
1590	Turbo-Puls	T-P 1000
2745	TURBO-PULS SYST.	T-P 1000

Table 4: This example shows the kind of confusion that can be created in a data system with the Make and Model entered as free text. The lack of consistency came to light after the data was imported into a new MEMS utilising the recommended data model (see figure 2).

The issues discussed here prompted HUH to start designing a new MEMS taking care of, amongst other things, the inventory part. A new data model was set up along with a new nomenclature designed in accordance with modern rules and techniques.

The Norwegian Project

In 1990, the CED at the University Hospital of Trondheim approached the National Board of Health with the aim to make a standard data model for Medical Equipment Management Systems (MEMS). This resulted in the formation of a committee comprising members from all of the five Regional (University) Hospitals, The Norwegian Institute for Hospital Research, Det norske Veritas (DnV) and the National Board of Health (SH). This committee issued the report *Specification of a technical administrative computer based maintenance system for clinical engineering departments*[19] in January 1991, taking on board many of the experiences gained from the Medical Equipment Management System (MEMS) project at HUH.

This report describes in detail the basic model for the representation of device data in the database, together with an elaborated model suggesting a maintenance system for medical equipment. These models are mainly intended for use by programmers that develop systems involving medical devices. Time has shown that the basic data model is equally useful for systems aimed at the CED workshop as for those used in vigilance and incident reporting and the like. Our claim is then:

> The basic model, used together with a standardised nomenclature and unambiguous coding of Device Types, will secure the possibility of accurate data exchange between all kinds of users which have this model implemented as a core in their systems.

The report concluded that a new nomenclature had to be developed, and that all Device Types should be registered in a unique and standardised way. A database containing this information should also be made available to all relevant users.

An initiative from the committee towards the National Board of Health resulted in the funding of a project for the development of a new nomenclature, and the start of a coding scheme for Device Types. The original committee was then transformed into a steering committee, and HUH was commissioned to undertake the work. An expert group counting nine members, of which eight members came from hospitals nationwide, and one from a supplier, were allocated to the project along with the necessary economic resources for a full time project secretary, and for travel/meeting expenses. The project was also asked to establish a network of contacts in Europe, and harmonise the efforts with ongoing work initiated by the CEC and the European Committee for Standardization (CEN).

The project started in April 1992, and the first version of the NKKN nomenclature was released in May 1993 ("The Green Book").[4] Alongside the development of the new nomenclature, the NKKN project team have been involved with the establishment of a national database for devices. This work is not yet finished, but all the necessary framework is developed and tested. The Device Type register is now offered on a preliminary basis. Our aim is to have a public database up and running by the end of 1994, and it will then be an offer to all kinds of users.

The team is also involved in the AIM/BEAM (Advanced Informatics in Medicine/Biomedical Equipment Assessment and Management) project, as well as CEN TC251/WG2 - *Health Care Terminology, Semantics and Knowledge Bases*, and will also participate in the recently established CEN TC257/Sub Committee 1 (SC1) - *Identification, coding, nomenclature and regulatory data set for medical devices*. NKKN views the establishment of the SC1 to be the most important step, taken by the Commission, towards actually achieving its goal of creating and implementing a common European classification and coding system for devices. Three work groups (WG's) are to be set up with the following mandates:

WG1 - Regulatory data set

To define the regulatory data set needed for data exchange to facilitate implementation of the MDD.

Note! In a meeting of CEC's DG III in February 1994, it was decided to transfer the planned activities of WG1 to the European Medical Devices Information Exchange System (EUROMEDIES) project, see below.

WG2 - General identification and coding

To develop a specification for an identification and coding system for medical devices to incorporate identification of coding elements such as nomenclature, manufacturer's identification number, model number and device class and to make recommendations for maintenance of the system.

WG3 - Nomenclature

To develop a specification for a nomenclature system for medical devices either by investigating and, if possible, adopting an existing system or by identifying an existing (or embryonic) system for further development (after development of a nomenclature system; to establish sub groups as necessary, to prepare a nomenclature for medical devices).

EUROMEDIES is a project initiated by DG III (Directorate General - Internal Market and Industrial Affairs) and, utilising experience gained from the AIM/BEAM project, will proceed with the work involved in developing a European information network for the exchange of information pertaining to devices. This project is naturally viewed as being an important part of the Nomenclature project and that the overall goal will be to support the harmonization procedure.

Under TC251/WG2, *Medical Informatics/Healthcare terminology, semantics and knowledge bases*, there has recently been established a new project team (PT2-015). The scope for its work is *Structure for coding systems of medical devices*. The work is scheduled to be completed during 1995.

Classification, an overview

The main purpose of a classification system for medical devices is to create the necessary foundation for unambiguous data exchange between involved parties, as well as supporting local functions like maintenance, purchase, vigilance, quality assurance, etc. Professionals acquainted with medical devices are familiar with several terms and concepts related to them; serial number, manufacturer, trade/brand name, model or type name/number, batch/ lot number, name/label, product category, group and so on.

After many years of experience with both manual and electronic MEMS systems at HUH it became apparent to us that we had to define a new basic data model, expanding it from the classical two level hierarchy to a three level hierarchy in order to achieve the goals mentioned above. This approach was later adopted as the basis for the new Norwegian model.

NOTE! It is absolutely essential that the reader now understands that the basic data model and data set only specifies the absolute bare minimum requirements for the system designer, other levels and terms may of course be introduced if so required. The data model was designed with only the ME category in mind, and it must most likely be modified to serve its intended purpose when it comes to the other categories of devices.

The three levels defined in the basic data model are as follows:

- *Device Group* is the top level, and is a general concept which is a term for a group of devices, like **Infusion, pump syringe** or **Defibrillator**. This is the level containing the nomenclature.

- *Device Type* is the middle level, and is the type or model name assigned by the manufacturer to the actual device in combination with the *Make* (usually the manufacturer's name) such as `IVAC 591`. It is of vital importance that a worldwide coding scheme for this level is devised and adhered to, see Chapter 7 and Appendix A for more details.

- *Device* is the lowest and most specific level, usually representing a real device defined by its *Device Type* designation combined with its serial or lot number.

Other levels can be added, like:

- Family name of a manufacturers specific product line of related *Device Type*s.

- Adapted or special version of *Device Types* (e.g. to comply with regulatory demands in a given country).

- Version number of software used as a part of the device.

Data model, naming the concepts and levels.

> **"Nomenclature development is not simply a matter of assigning a name and a number to each device. It is far more complicated, involving systems architecture, coding, consistency and vocabulary control."**
>
> [Dr. *Joel J. Nobel*, ECRI, USA at The first international workshop on harmonization of medical devices nomenclature, Brussels, November, 1991]

The first problem which has to be solved when making a classification system is to achieve a general agreement on the number of levels which should be defined, and to decide upon what to call them. Without such an agreement much confusion and apparent disagreement will arise, because the terms used today both in spoken and written form are highly ambiguous. A classical example is the AIM/BEAM project which has failed to reach some of its prime goals because this simple fact was overlooked/ignored by the project participants. This has resulted in some of their documents being difficult to comprehend, unless they are furnished with a definition of terms.

Examples of ambiguous terms:

Group, category, class, type, family.
Sub-class, division, family.
Manufacturer, producer, factory, company.
Supplier, sales office, agent, distributor.
Trade name, brand name, model, type, manufacture, make.
Batch, lot, variant, version.

The terms finally selected for the Norwegian standard are based on careful interpretation of the terms used in IEC 601-1[5] and the MDD[1].

The Norwegian data model for the classification of Medical Devices

Device Group is the traditional nomenclature level, which is a list of preferred terms and synonyms (admitted terms) naming the devices in a general way. No company proprietary terms are normally allowed at this level. In other nomenclatures this level is called *Device Categories*, *Device Classes*, even *Device Types*, etc.

One reason for choosing the term *Device Group* for this level is the fact that it is a rarely used term which apparently does not have any ambiguous meaning. The reason for not selecting the term *Device Category* is that we have reserved this for a higher level, and the term *Device Class* may be (mis)interpreted as *Risc Class* as defined in the MDD[1].

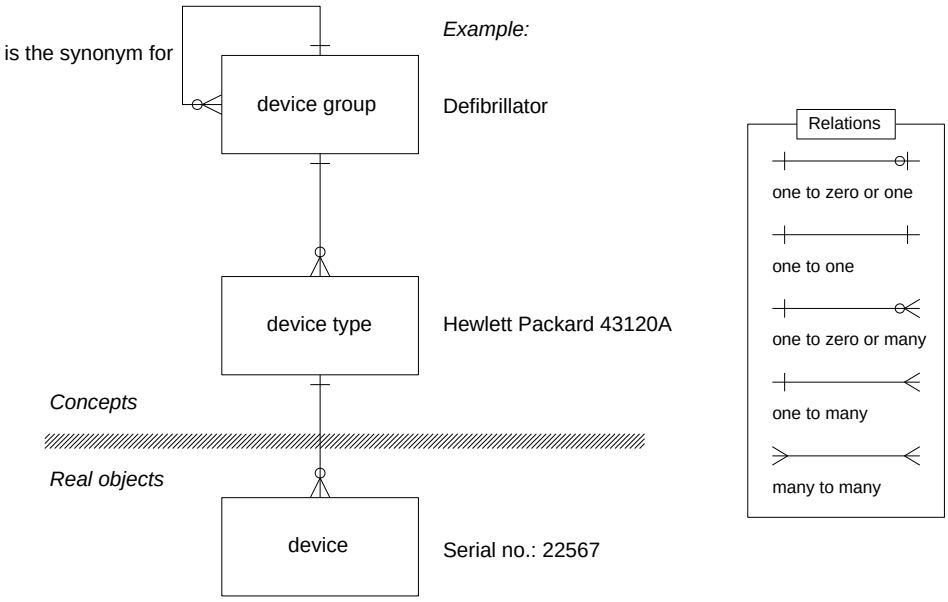


Figure 2: The Norwegian data model.

Examples of *Device Groups*:

Analyser, oxygen
Audiometer, clinical
Cardiotocograph
Defibrillator
Heater, blood

The *Device Type* level are the names for the make, type and/or model found on a series of identical devices from a manufacturer. This level includes fields (terms) like make, type, model and family name. Other classification systems may use the terms *Device Model*, *Brand*, *Trade name*, *Lot* or maybe *Batch* for this level. A *Device Type* is related to one, and only one, *Device Group*.

The reason for choosing the term *Device Type* is that *Type* is the most common denomination to be found on the device's label (on European made devices). IEC 601-1[5] (EN60601-1) standard also refers to "model or type reference (type number)". Our definition is equivalent to the "type" defined in *Annex III: (EC type-examination)* in the MDD[1] from CEC.

Examples of *Device Groups* with related *Device Types*:

Device Group	Device Type
Analyser, oxygen	Bio-Tek 74223 Ohmeda 5100 Siemens-Elema E037E-02A 110 Teledyne TED 60T
Infusion, pump syringe	Criticon Syringe-Minder 90 Graseby Medical 3100 Ivac 770 Ohmeda 9000 Syringe Pump

The two highest levels described are mental constructions or concepts used for classifying the devices in an orderly and useful way for the professionals using these levels. It may be a cause for theoretical discussion whether or not the *Device Type* level is a mental construction since these names are printed somewhere on the equipment, usually on the label. This discussion is best left to the philosophers, and in the data model we treat *Device Type* names as concepts.

It is in the lowest level that the "real world" objects occur; the devices. This is the representation of each singular device, uniquely identifiable by the combination of the *Device Type* designation and the serial number. In a hospital, a device can also be uniquely identified by its inventory number, provided this has been assigned. A *Device* is always related to one, and only one *Device Type*.

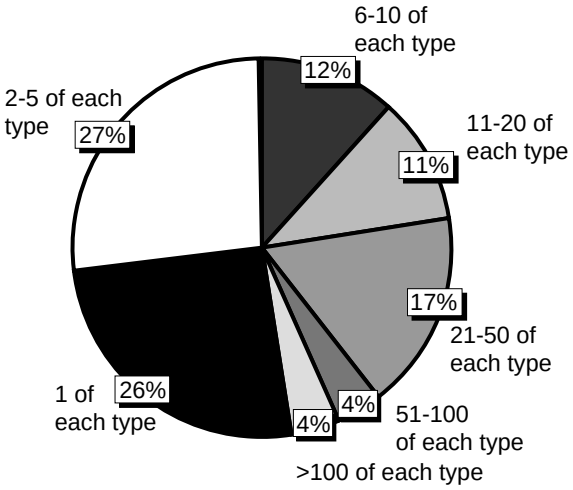


Figure 3: Distribution of identical Device Types.

It may be of interest to the reader to see a "real life" example (figure 3) of the device vs. Device Type distribution in a large hospital (HUH) comprising 7837 devices of 3033 different Device Types. 2027 of the Device Types (26 %) are only being represented by one single device each. 425 Device Types have 2 devices each. The average number of devices per Device Type is 2.6. Only three Device Types have more than 100 devices, these are infusion pumps, apnoea alarms and tympanic thermometers. Simpler equipment like oxygen therapy flowmeters and wall mounted, gas driven suction units are not registered nor listed in the inventory.

Since 74% of the devices exist as two or more species, there is clearly a need to name the identical devices in an identical way.

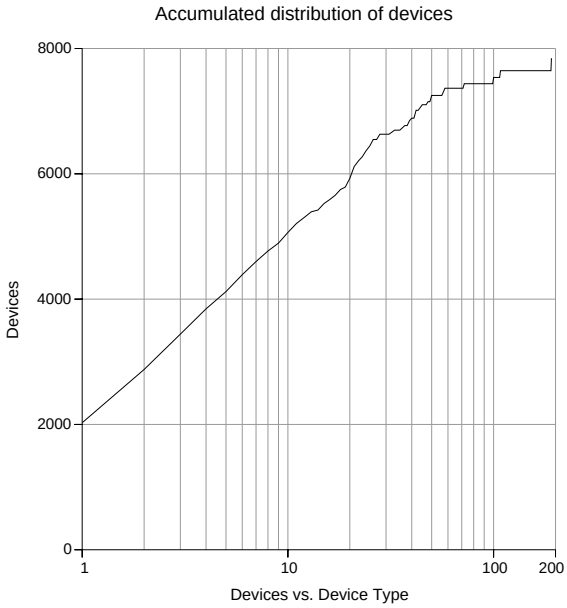


Figure 4: Accumulated distribution of devices.

Figure 4 shows the same distribution as in figure 3, but with the number of devices shown accumulated on the vertical axis. Since the horizontal axis spans from 1 to 191 devices per Device Type, and since many possibilities do not exist, a logarithmic axis is used. The median, comprising 50% on each side, is 4.3 devices per Device Type. The data set used to generate the curve reflects devices, from a large number of manufacturers and suppliers, obtained during the last 15 - 20 years. It is therefore a bit surprising that the curve will nearly fit a straight line in this representation. We hereby encourage other CED's to compare their distribution of devices vs. Device Types with our findings, in order to see if there is any match. The curve reflects the degree of standardisation of Device Types in the hospital.

The use and users of the classification system

Introduction

As with all commodities, services and transactions there are always many parties of interest; some not so obvious as others, but nevertheless each of whom view their participation in the dealings as being of importance. They may not even be aware of one another nor consider the needs of other parties. This has hitherto most certainly been the case regarding medical devices. Equipment manufacturers will fulfil their own special needs for traceability for production and sales through their specific parts numbers and labelling. Equipment distributors and suppliers will relate to sales brochures that incidentally, usually provide a very generalised description of the products or series of related products, and internal product/catalogue numbers. Equipment test labs will certainly have a need to relate test results to the product prior to release upon the market, whilst the user, hospitals and health services have an acute need for access to all relevant information as they constantly evaluate products prior to acquisition and bring them into use. The user will invariably be obliged to invent their own inventory systems and internal catalogues and thereby be unable to exchange data with their contemporaries, thus becoming isolated islands of first-hand information. The authorities, who are incidentally the people rarely in contact with the actual products, face the greatest challenge of all through the enforcement of the MDD—and are now obliged to implement national vigilance systems that eventually will interactively connect to some kind of European database.

As of today and until a common European system is up and running, all of these potential needs will be totally disjointed. Traditionally, we have all been too preoccupied with the idea that traceability could be achieved through the nomenclature alone, and that this would achieve the above mentioned ambitions. This is a misconception and is probably the main reason why, despite an abundance of nomenclatures many of which are quite good at face value, there is still no viable system that can be readily adopted as a European concept. We *must* abandon this train of thoughts entirely and look at the problem anew. The issue is then, how to achieve unambiguous identification of the devices themselves?

The central object of interest, for all the involved parties, is the medical device itself. By bringing this into focus, the scenario will look something like in figure 5, taken from our proposal *A Common European Nomenclature and Coding System for Medical Devices*.[6]

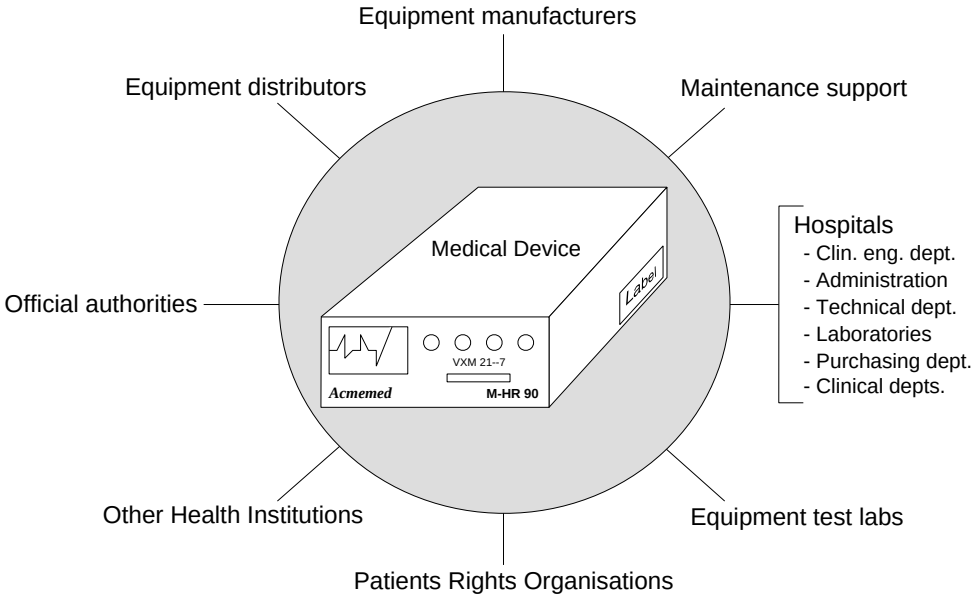


Figure 5: Parties focusing on the medical device.

The different parties have different points of view according to their needs, and for "our sector" (Authorities, Hospitals and Other Health Institutions), these would be:

Authorities

- Vigilance
- Recalls
- Regulations, special demands, etc.

Hospitals and Other Health Institutions

- Purchasing
- Use
- Maintenance
- Inventory
- Condemnation
- QA/QC

Our experience has shown us that the labelling employed by the manufacturers to identify their products are at the best, useful, and at the worst, highly confusing. There is clearly a need to standardise labelling in order to exclude the possibility of ambiguous data being entered into whatever system. It is no secret that NKKN would like to see a mandatory, and hopefully infallible coding scheme for medical devices implemented worldwide as soon as

possible. Such a coding scheme may in fact calm down the discussions about which nomenclature system the world should choose, this since different nomenclatures may happily coexist within this new coding scheme. If at this stage, anyone has doubts about the feasibility of achieving this goal, just take a trip to the local super market and look at the various goods sold there. It should, in principle, be no worse for the manufacturers of medical devices than it is for manufacturers of whatever goods sold in a store to code their products in a unique way. It might be correctly pointed out that many devices are a composite of different parts or elements such as; treadmill, computer, monitor, ECG-unit, combined could be a stress test unit—and therefore somewhat more difficult to identify than one carton of ground filter coffee found in the store. This is the challenge we must take up together in order to devise an adequate scheme that the manufacturers will see the importance of adopting.

The authorities

In Europe, the MDD will be enforced from 1.1.1995 (MDD[1] Article 22 §1). This will lead to a new situation for all parties involved with medical devices. One of the more important issues in this directive is the new Medical Devices Vigilance Systems (MDVS) which is to be set up as a European system run by the national competent authorities. The data collected as a result of this need is to be disseminated to all EU member countries in an effective and secure manner. To accomplish this there is an acute need for a classification system for medical devices. One example demonstrating the need for a coding scheme that can take care of the Device Type level would be the notified bodies who must be able to communicate various information related to the devices, such as type certificates, the manufacturers register, and so on. One example illustrating the need for the Device Type level is that if a device is rejected by one Notified Body, then the manufacturer is not allowed to apply for certification by another Notified Body.

The authorities and the standardising organisations issue regulations and standards concerning a broad range of products. These bodies usually use broad terms which sometimes need careful interpretation before they can be related to the "real world" devices concerned. Here one sees a need to classify the products in order to simplify the correlation of products to regulations, and conversely, this would also make it easier for the authorities to investigate which products an existing or planned regulation would concern.

Unambiguous communication with the owners and users of the devices is essential for the authorities in order to implement their regulations and control that they are complied to.

If an act, regulation or standard were to be implemented in several countries with different languages, and because of this must be translated from one language to another, new problems emerge. The reason for this is that no official standardised cross-nomenclature for the devices exist in the different languages used across Europe. This must be taken care of, and within the NKKN project we have already loosely played around with this problem and have seen that it can be easily overcome.

Example of issues covered by acts and regulations:

- Pollution control.
- Exposure to radiation.
- Sterile products.
- Electromagnetic compliance.
- Electrical safety for patients and users.
- Procedures and accuracy in measuring.

The regulations are indeed numerous, and the user/owner of a device is responsible for the compliance with relevant regulations. It is at present, very difficult and time consuming for the users to trace the relevant regulations for new devices, and much time is wasted in telephone conversations and correspondence in an attempt to disclose what regulations concern the particular device that is now going to be purchased (or in reality: is purchased). Therefore users will warmly welcome such a coding scheme.

The Competent Authorities

The Competent Authority will be a central player in the MDVS, and will be represented by the Health Authorities in each of the participating countries. Their main job will be to establish a surveillance system for incidents related to medical devices, and to ensure that remedial or corrective actions are carried out in accordance with the directives. It is in itself a formidable task to be undertaken, and will be totally dependent upon a smooth running data exchange system. National vigilance reports having certain properties (like degree of severity) have to be distributed within the European MDVS by the national Competent Authorities.

The National Board of Health has presented the following list showing the authorities requirements and intentions for use of the classification system:

- Identify devices involved in incidents/accidents.
- Supervision of the medical electrical equipment at the institutions.
- Review, on a regular basis, of each institution's quality management systems.
- Collect operational data on different types/groups of devices.
- International exchange of data concerning experience and accidents with devices.
- Maintaining of the manufacturers registration approval.
- Contribute to the secure and economic running of hospitals.
- Database/knowledge bank on devices for issues such as; risk, economy, clinical effect, etc.
- Contribute data to standardisation work and product development.
- Pre and post market surveillance.
- Information of Notified Bodies and conformity assessments.

[Source: Jacob W. Nordan, Directorate of Health, Norway.]

Notified Bodies

Traditionally, the process of certification of Medical Devices—especially MEE's—for technical approval and hence release for sale has so far been a national interest, and the certification was given after rigorous testing by the national test house. Since a product made, let us say in Germany, would first be tested and approved on its home market by TÜV, it would then have to be tested repetitively in all other European countries where it was to be sold—BSI in Great Britain, SEMKO in Sweden, NEMKO in Norway and so on. These test houses were not compelled to exchange information and hence, their report files would be supported by an internal classification system.

The new era of the one singular EU market, with a free flow of Medical Devices, has resulted in that product clearance by one Notified Body will be sufficient for free sale across the entire market. The affixing of the CE-mark will provide the proof that the product complies to all necessary and relevant standards. Notified Bodies, approved by their national Competent Authority, will monitor and assist these proceedings. It is perfectly clear that without a workable classification and coding system the Notified Bodies will not be able to function as envisaged in the MDD.[1]

Manufacturers, suppliers

Companies that manufacture or distribute devices may also see the advantages of a standardised classification system. For example: Easier access to potential customers, facilitate communication with non-experts, or to enter information about their products in a precise manner in databases used for purchase/information. Such a databases may also contain additional information that the manufacturer would desire to present about his products. The system may also be a useful contribution to the Tender Electronic Daily (TED) system which has to be used for purchases over ECU 200,000.

However, in sales and marketing, it might be considered disadvantageous to have one's own "very special" products listed together with the competitors "ordinary" goods. It is therefore theoretically possible that some manufacturers want specific divisions in a classification system highlighting their own products.

Hospitals

The hospitals are, not surprisingly, heavily involved in the use of devices. A standardised classification system will be beneficial to many of the professions involved with medical devices. These professions include logistics, maintenance, quality control, planning, nursing and so on.

The Clinical Engineering Department (CED)

Some of the many tasks performed by the CED are; the upkeep of an inventory for ME, propose replacement requirements and maintain the hospital's ME. Of course all of us

would far rather enjoy bathing in the sunshine on some Caribbean island instead of wasting our precious time doing this tedious work. Nevertheless, a large hospital in Norway will typically contain 3000 - 8000 pieces of equipment ranging from 1000 - 3000 different Device Types. The idea of this classification system originated from the CED in the first place, so we are quite convinced that the CED has a definite need for such a system. One of —the first needs that comes into our minds is that of the poor maintenance engineer, when struggling to carry out a repair, has to scan the whole database for a clue to a strange failure with a device that his colleague experienced two years ago—or was it three?—with a similar device. Without a good system the poor chap has to scan perhaps some ten thousand maintenance jobs in the maintenance system to find the vital clue. We are quite sure that he is already standing at the counter of the nearest travel agency, flicking through an airline timetable, even before considering that task...

We believe that the CED is one of the more important sources of data related to medical equipment which may be of interest to the authorities. A common classification system will ensure that it is feasible to extract such data from the local MEMS systems for direct use by the authorities.

The clinical engineers usually have their own conception of Device Types, and it can be described as follows:

A Device Type denotes an identical production series of Medical Equipment, its parts or accessories— designated by a text which is assigned by its manufacturer and then applied to the device's surface in a simple, explicit and—hopefully—identical way throughout its production.

The same technical specifications, environmental demands, service needs, manufacturer, user manual, service manual, spare parts, sales arguments, user and service training, technical life expectancy, benefits and inconveniences and approximately the same purchase price applies to all devices of a given Device Type. Also, all devices of a given Device Type are usually easily recognised by having the same colour and appearance.

The Purchasing Department

The Purchasing Department normally controls the procurement of medical devices to the hospital. This applies both to the consumables like single use sterile products and to capital goods like Computer Tomographs. If a common classification system is successfully implemented as sketched within this book, it would undoubtedly simplify the process of tender, both nationally and throughout the Common Market alleviating the mechanisms for the free flow of products.

It is our conviction that the development of a nomenclature, not just for devices, but for all health sector products would significantly boost the capabilities and potential of the Purchasing Department.

Clinical Departments

The Clinical Department, like the hospital's administration, has a need for access to a device inventory. The authorities have regulations for quality control which, among other things, requires the systematic training of staff in the use of medical equipment, and regulations for procuring, installation, use, service and disposal of medical equipment.
The clinical departments are in regular contact with the CED. Therefore the CED staff are acquainted with the different terms (often local jargon) departments use to name the devices. A standardised nomenclature will hopefully, when adopted, contribute to less confusion, and perhaps toward a reduction in incidents, which can occur when using today's local jargon. When procuring relatively conventional medical devices a classification system will be beneficial to the clinical departments.

When producing data for long term budgeting, a clinical department will prefer methods using the clinical lifetime for the devices. The clinical lifetime is based upon how long a diagnostic, therapeutic or monitoring method is valid or "up to date" in a clinical, economic or public-appealing/acceptable manner. This lifetime is usually shorter than the technical lifetime, which is based only on patient safety and running/service expenses.
In general a clinical department would more often than a CED prefer to classify the devices according to the patients' needs and diagnostic/therapeutic method. ("*This year's department budget for medical equipment for our heart patients is only X ECU!*"). On the other hand we have the impression that the clinical departments usually appreciate and understand the work the CED does in the upkeep of an updated inventory, and this is why they, as long as they do not disagree with the chosen terms in the nomenclature, accept without objection the classifications done by the CED.

Other hospital departments which are concerned with devices are the Transport department, Department for Computers and Information Technology, and Department of Radiotherapy.

The public, mass media

Regularly voluntary actions are initiated by interest groups or beneficial organisations to raise money for new equipment at a local hospital. The motive could be idealistic, emotional, district political or other. Newspapers willingly cover the story. The ME involved is usually a high-tech device for diagnosis or treatment within a relatively limited medical speciality, and which the hospital owner could ill afford to give priority to due to lack of financing. Also it might be equipment which the government has decided should only be situated in one, or a few of the major, hospitals in the country, because the equipment is so expensive and requires highly specialised staff and a high number of patients. (In Norway

A story from our hospital, said to be true, illustrates the benefit of not having a standardised nomenclature: A clinical department had for years listed a large mirror on their next annual budget. This mirror was to be used for patient training/exercise, and cost less than ECU100. Year after year the mirror was removed from their budget by the administration. One year the department had their next annual budget written by an inventive new staff member who knew the procedures and habits of the administration. She then put on the budget a *Human Reflector* at the cost of ECU 1000. Of course no one dared to remove such a specialised device from the budget!

there are only 4 million inhabitants, and almost every hospital is run by the authorities.) To a local community in Norway such a governmental decision is, in itself, a very good reason to obtain the equipment for their hospital. To create interest and goodwill for donations, and also to explain to the public what prospects the equipment possesses, fantasy words are invented to name the equipment. A good example is *Body Eye* used as a sensational fictitious synonym for Magnetic Resonance Imaging. In general, mass media will probably not have any interest in a standardised nomenclature.

Quality control

Without regard to the chosen system for quality control, its implementation presumes that the hospital keeps an inventory of its devices.[7]

The first letter from the National Board of Health to the Regional Hospitals (April 1990) "*Administrative management system for medical devices*" which initiated the work on a standard data model, and which in turn initiated the Nomenclature Project, starts with this sentence: "*The introduction of quality control for the use of medical devices, requires the hospitals to have a technical administrative system for the administration of the devices.*"

General internal control in a company or institution implies a need to identify the regulations related to medical devices:

The internal control implies:

- All relevant regulations must be identified: including resolutions, injunctions, etc.
- All regulations must be included in specifications/particulars of products, services, plans and programmes.
- Planning, organisation and execution in accordance with these requirements.
- Keeping up to date with alterations in legal provisions, regulations, etc. in a systematic manner.

In short: Use the quality loop on acts and regulations.

[Source: Man. Dir. Egil Haugland, Haukeland University Hospital, Bergen.]

By *internal control* is understood the actions taken by a company in order to ensure that all its activities are in accordance with regulations and laws. This also implies, as outlined above, the necessity of identifying all regulations related to medical devices.

In other words, the classification system discussed in this book is imperative in order to use the hospitals inventory for the purpose of quality control, and to allow the authorities to submit their device related reports back to theirs and others quality control systems.

Nomenclature Design

In every MEMS or other data system concerning medical devices there must be access to a nomenclature. This nomenclature must, at least, contain the needed number of terms to cover the categories of medical devices which is to be registered in the database. *Which* terms to include, depends upon the needs of the actual user. The consequence of this is that the nomenclature has to be designed with the different uses in mind—whether this is vigilance reporting, inventory purposes, purchasing, etc. This is an important demand which had to be complied with by NKKN, that the nomenclature should adequately fulfil all the users needs independent of the their background, avoiding the risk of creating several nomenclatures each meant for a limited user group or use.

The development of a nomenclature for medical devices can be compared to tightrope walking: Too much weight on one side of the centre will make you fall—transferred to nomenclature development this will be: Put equal parts of philosophy, structure, experience and common sense into it, otherwise you just create nonsense.

What is a nomenclature entry? Is it just the name of a medical device to be added in a hurry when one has a need for it? In our opinion, it is not that simple at all, even though it appears that many nomenclatures have evolved in this manner. Again, we feel it is necessary to quote Joel J. Nobel, president of the ECRI-institute:

"*Nomenclature development is not simply a matter of assigning a name and a number to each device. It is far more complicated, involving systems architecture, coding, consistency and vocabulary control*."

A nomenclature entry can, in this context, be very shortly defined as:

A nomenclature entry is the chosen designation (name or term) for a Device Type.

In the NKKN nomenclature new entries are added only after the careful consideration of the following three factors, this to ascertain that there is a *real need* for a new term:

- It must be possible to classify the device using a term that can be widely accepted.
- Is the device a composite device which should be considered as several devices covered by more than one term?
- Is the device an (expensive) accessory which for some reason requires a separate entry?

The three above mentioned factors will be further discussed and embellished:

It must be possible to classify the devices using a term that can be widely accepted.

The preferred terms selected to make up the nomenclature should be, *whenever possible*, widely accepted by the various professions, suppliers, manufacturers and other involved parties. This, of course, is to encourage the use of the nomenclature everyday communication. Humans will of course never accept or get used to the idea of speaking backwards, asking for e.g. an *Analyser, blood gas*, but will most likely be referring to the object as a *Blood gas analyser*. However, when creating terms for the nomenclature it will be both rational and structurally correct to use the "backward" method. This is the main philosophy behind the guidelines for the NKKN nomenclature, ref. Chapter 6. We must stress the importance of adhering to these predefined guidelines, otherwise anomalies will most likely creep in and eventually break down the nomenclature.

The expression *communication* can have different interpretations, for instance: Exchange of information in data systems, presentation of information (via any medium), conversation between two or more persons, etc.

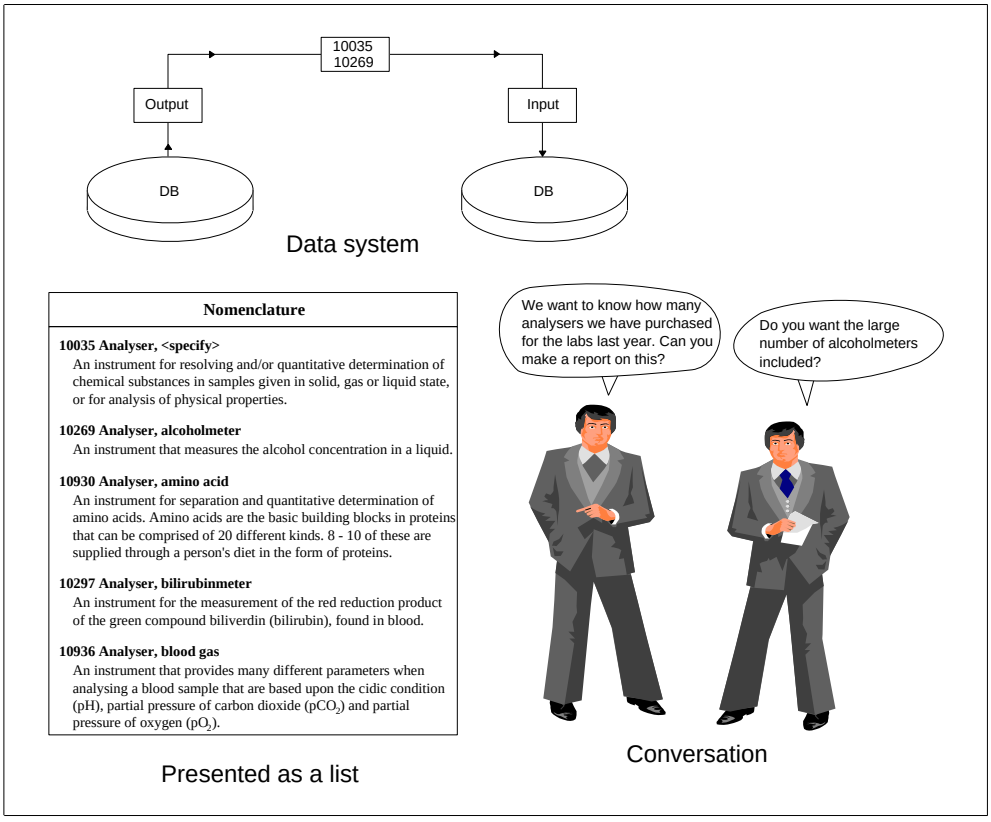


Figure 6: Various forms of communication.

Figure 6 shows that there are different forms of communication using different ways of transmission, transformation, presentation and interpretation of information. Data systems demand clear and unambiguous information, this because they cannot "discuss" the contents of it, whilst on the other hand, human beings are quite capable of doing so if they are in doubts about the meaning. When humans exchange information about e.g. a new device from *Technicon*, we do not normally ask "*What are your experiences with Technicon 113-A009-01?*", we would rather ask something like "*What are your experiences with the new haematology analyser from Technicon?*" These simple facts creates the starting point for adding a new term to the nomenclature.

Manufacturers often create their own terms when advertising new products. A manufacturer will of course try to exploit the advantages of his new term being used instead of a term from an official nomenclature. An example from HUH illustrates this: In our institution it is quite common to use the term *Dinamap* in speech instead of the preferred term *Sphygmo-manometer, electronic*. This will tend to favour the manufacturer producing this equipment under the brand name *Dinamap* when a user is deciding what type of equipment to buy, because he/she may perceive a *Sphygmomanometer*, *electronic* through this particular brand name. We regularly observe advertisements introducing "new technology" that apparently create the need for new terms in the nomenclature in accordance with the manufacturer's new marketing slogan name. But, after closer investigation, it often appears to be just an improvement or modification of existing equipment, and it can be classified using an appropriate existing term.

On the other hand, the fast development of medical technology frequently necessitates the adding of new terms. A good nomenclature cannot remain static and should therefore reflect technological development, and must be frequently reviewed and kept updated in order to meet the influx of new technology *before* it is available on the market.

Is the device a composite device which should be considered as several devices covered by more than one term?

Some medical devices are composed of a set of units which, in some circumstances, has to be regarded as separate devices in themselves. This fact typically applies to X-ray equipment found in X-ray laboratories, Computer Tomographs (CT) and other complex installations. There is a potential conflict with the classification of such devices, this due to fact that different users of the nomenclature may have different views on what level of detail that is required (in the nomenclature). An administrator may typically only be interested in information relating to e.g. a *Computer Tomograph*, and he has generally no idea about the different units that together makes up this device. On the other hand a clinical engineer will normally have a different, and more detailed, approach to the CT. The following example (figure 7) illustrates this:

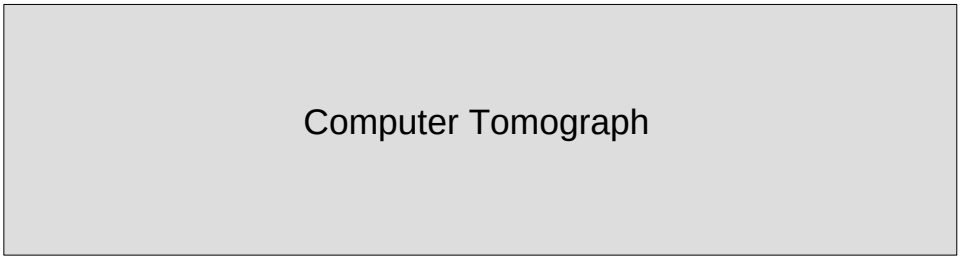


Figure 7: Computer Tomograph regarded as one device.

An administrator who is going to calculate the CT coverage in the country, will only need to know the actual number of CT installations. He will then, of course, regard the CT as a single device.

When searching in the database containing the information needed, the administrator will most probably be looking for the term CT. But, when dealing with "the real world", the picture should look more like shown i figure 8—especially when it comes to satisfy the needs of the clinical engineers.

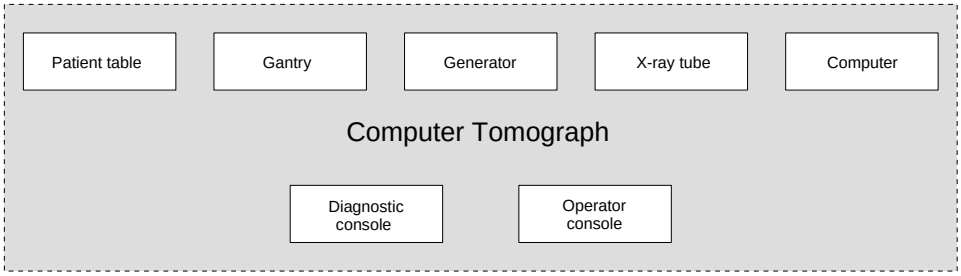


Figure 8: Computer Tomograph regarded as a composite device.

As shown in figure 8, a CT consists of many different devices that together makes up the complete installation. In a MEMS, all these devices ought to be registered separately to accommodate the demand for gaining a complete survey regarding; failures, maintenance costs for each unit, etc. One does not, of course, replace the whole CT if one of the component devices develops a failure.

Typically, the X-ray tube will need to be replaced every third year, or a specific PC-board in the computer might be causing a malfunction; such data will have to be logged into the device history log. Rapid and successful retrieval of this information will undoubtedly have direct implications for minimising "down time". Accident reports supporting a country's vigilance system will depend upon concise information, and specificity/traceability etc. will play a very important role.

By breaking down the CT using more specific terms as described above, a database containing the information related to the running and maintenance for each single unit of the CT will be built up providing an informative device record. The database system will then enable the clinical engineer to track down repeating errors in one part of the CT with relative ease. Should, on the other hand, all the records of errors and events have been registered using *only one* term, e.g. *CT*, the mass of information would be voluminous and very cumbersome to handle, running easily into hundreds of records. From a vigilance system point of view the matter becomes infinitely more complicated if reported events should be related to a singular term, e.g. *CT*. It goes without saying that the reported event will be more valuable and informative in proportion to the amount of the detail supplied. Supposing there has been an accident because of failure with the *CT-table*, then the information should be related to a more specific term, like *CT, table*. This, coupled with the Device Type, will enable hospitals to report to Competent Authorities who in turn can transfer/relate information to the Notified Bodies, manufacturers, suppliers, etc. in an unambiguous manner.

When considering this, it can be stated that a composite device should not necessarily be classified using *just one* term in the nomenclature. The nomenclature should in fact be detailed enough to support the classification of composite devices in an appropriate manner. If we, once again, take a look at the example of the CT, the nomenclature may contain the following terms in order to meet the need of the users:

CT, <specify>
- **CT, computer unit**
- **CT, diagnostic console**
- **CT, gantry**
- *CT, generator* - see **X-ray, generator**
- **CT, operator console**
- *CT, store unit* - see **Computer, <specify>**
- **CT, table examination**
- *CT, tube* - see **X-ray, tube**

The nomenclature listed in this example divides the CT into units, enabling the user to register the devices that make up the CT separately. However, in order to handle the CT as one object, a well-designed MEMS will usually support the notion of installations, allowing the user to link the component devices to an installation like *CT-lab 1*, *CT-lab 2*, etc. In this way it is possible to handle the different devices separately or as one installation, and the required traceability is then taken care of.

Is the device an (expensive) accessory which for some reason requires a separate entry?

> ""accessory" means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;" [MDD Article 1 §2 (b)]

A device often needs to be connected to what is termed as accessories in order to fulfil its intended purpose. As an example; an ultrasound imager cannot be used if there is no ultrasound probe connected. When purchasing this type of equipment, the probe(s) are usually included in the total cost of the device, and since the probe(s) might be regarded as an accessory it would not be unreasonable to register the probes along with the main device, e.g. in an accessories field, and leave it at that. However, there are some important issues to consider when dealing with ultrasound probes:

- They are expensive to buy, in Norway the price range is normally ECU 6.000 - 11.000, and up to ECU 75.000 for special types.
- They have a relatively short life-time, approximately three to five years.
- They are very susceptible to damage and are very expensive to repair.

Primarily, the costs entailed in the purchase and upkeep of ultrasound probes is in itself more than reason enough for a more detailed nomenclature supporting the separate registration of such kinds of accessories. This then allows us to achieve the following:

- Avoid probe events being recorded as *Ultrasound imager* events.
- Reveal the real ultrasound probe costs (for a particular scanner).
- Keep an event record for each probe.

Of course this argumentation applies to all accessories that have the same inherent features as discussed for the ultrasound probes.

Some common nomenclature pitfalls

During the development of the new NKKN nomenclature we have of course made our share of mistakes. We have analysed other nomenclatures like: NIS/DIS, UN[9], NATO[10], FDA[11], BEAM[12], UMDNS[13], EMTEC[14], The Italian[8] and several other non-medical ones in order to avoid the problems apparent in these. The development of a nomenclature is a continuous process, and the experiences from the "early days" have been of immense value and helped us to learn about, and avoid, what we now call "nomenclature pitfalls". Indeed, we have made a set of strict and comprehensive rules and guidelines describing the process of creating and maintaining a nomenclature (ref. Chapter 6). Still some of these shortcomings can only be avoided by the experience achieved through the method of trial and error, and we would like to discuss some of them:

Nomenclatures that are too detailed

When persons who devise nomenclatures focus too heavily upon their own field of interest, they invariably make the mistake of embellishing their particular field of interest, and in this way creates a nomenclature that is most likely too detailed. In fact, the more detailed a nomenclature is, the harder it is to classify a device in a precise manner†. From our own experience, we have seen the consequences of a too detailed nomenclature, e.g. a rather ordinary term such as a *Defibrillator* may be split up into many new terms to satisfy different technical solutions, which then in a short period of time might begin to overlap one another. It can easily follow, that for each new technical innovation, a new term has to be added. This will most likely lead to a nomenclature that, with the intention of being very specific, becomes cluttered and bothersome to use because of the overlapping terms. A simple example are the terms *Defibrillator, Battery Powered* and *Defibrillator, Line Powered* from the 1992 edition of the UMDNS nomenclature[13], which no longer applies to reality since most defibrillators of today are both mains and battery powered. It follows from this that one should be extremely careful when adding new terms, in order to avoid such problems in the future.

There is of course the deeper and more hidden reason why most nomenclatures; especially those concerning complicated products such as Medical Devices, become too detailed and hence, incomprehensible. Because they are not used in conjunction with a Device Type level (as described in Chapter 7), the construction of the nomenclature will bear distinctive signs of this fact which can be seen in the amount of elaboration created as a compensation for this deficiency.

Abstract terms

Nomenclature designers not familiar with the use and function of the specific medical devices to be covered by the nomenclature may often have a rather theoretical knowledge of them. This can lead to the construction of what we call *abstract terms.* These terms have the common feature that there are no "real world" devices that can be classified using them.

An example from HUH: The term *MR, coil body* was added together with other MR coils *(MR, coil skull, MR, coil extremity*, etc.). This seemed to be natural and appropriate in order to cover all the different MR coils. But, when we set about the task of actually registering a new MR installation at our hospital, we found that the body coil was in fact part of the gantry (which was already covered by the term *MR, gantry*). Since the body coil was an

†Be aware of this paradoxical matter: Inexperienced designers of nomenclatures often claim that a very detailed or highly specific nomenclature will make it easier to select the correct term for a device. The opposite is the truth: The more detailed a nomenclature, the harder it is select the correct term. The simple reason for this is—in addition to the obvious fact that few terms gives easier selection—that due to the rapid development of new technologies, detailed or highly specific terms in the nomenclature will be prone to become inadequate and even ambiguous.

integral part of the gantry, and since it cannot be regarded as a separate device, we then decided to remove the term *MR, coil body* from the nomenclature. It was a fictitious, abstract term.

Synonymous terms

In many nomenclatures we find terms that are, by way of our viewpoint, synonyms to the preferred term. This seems to be a common mistake, and we believe the reasons for the occurrence of such "false" terms are:

- The traditional habit of naming a device by a synonym (to the preferred term).
- Too little investigation into a device's real function.
- The manufacturers use of terms has influenced the nomenclature designer.
- No support for *real* synonyms in the nomenclature (lack of system support).

We have picked a few terms from different nomenclatures that can serve as examples:

In the Italian nomenclature[8], there is a term called **Endoscopio**. This is an preferred term or template term in most nomenclatures. But when looking through the list starting from the letter A, one can find:

Arterioscopia
Artroscopia
Broncoscopia
Cistoscopia
etc...

The mentioned terms are all endoscopes, and the term **Endoscopia** can be used instead of all the other terms ending on **...scopia**. The result can be that some bronchoscopes will be found under the term **Broncoscopia**, and some under the term **Endoscopia**.

In the 1992 edition of the UMDNS nomenclature[13] one can find the following terms that all concerns defibrillators:

Defibrillators [11-132] Category expanded below.
Defibrillators, Automatic [17-438] Category expanded below.
Defibrillators, Automatic, External [17-116]
Defibrillators, Automatic, Implantable [16-652]
Defibrillators, Battery Powered [11-134]
Defibrillators, Implantable - see Defibrillators, Automatic, Implantable
etc...

We will not comment on this way of dividing the defibrillator into all these subdivisions, but would like to bring attention to the two terms **Defibrillators, Battery Powered** and **Defibrillators, Line Powered**. As mentioned in the paragraph *Nomenclatures that are too detailed*, most defibrillators today are both mains and battery operated. In our opinion, the two mentioned terms are ambiguous and should be replaced by the term **Defibrillators.** The terms **Defibrillators, Battery Powered** and **Defibrillators, Line Powered** could then serve as synonyms to the preferred term.

It is advantageous that a nomenclature contains synonyms that cover most of the everyday used terms, thus making it easier to use. The only disadvantage is that printed nomenclature lists then tends to become very long, but we can accept this due to the fact that today nomenclatures are mostly used in data systems. However, it is important that the synonymous terms are handled as such—they should only be used for looking up the preferred term. Another matter worth mentioning is that the addition of *artificial* synonyms never used in everyday speech should be avoided.

Multi-function devices

The growth of multi-function devices has, in the course of recent times, been significant, and this trend appears to be increasing in magnitude. This fact has lead to an ever increasing extent of complexity in the task of classifying medical devices. Most existing nomenclatures have not been updated to provide for this development.

How can we classify a device that can serve as both an *ECG-monitor*, an *Electronic sphygmomanometer* and a *Pulse oximeter* without resorting to a "many-to-many" relation between the nomenclature term and the actual Device Types? To be honest, we have not found the ideal solution yet! (and we regard the "many-to-many" relation to be cumbersome in practical systems) Whilst we are still searching for the optimal answer, we classify in the following manner:

One has to decide which function or method with the device that is the most significant, and classify the device in accordance with this decision. A device possessing the properties as described in the example above, would be classified as *Monitoring, bed-side unit* in the NKKN nomenclature.

We do not consider it a good idea to make a template such as *Multi-function, <specify>*, because of the nondescript nature of the term *Multi-function*. Other templates, such as *Analyser, <specify>*, *Infusion, <specify>* or *X-ray, <specify>* gives the user an instant idea of what is listed under the actual template, but what is *Multi-function* telling him or she?

Who should develop and update/maintain the nomenclature?

The matters described above should also reflect who should be responsible for developing and maintaining a nomenclature. It must be clear that this ought to be managed by the nomenclature users in collaboration with the equipment manufacturers. We have experienced that when experts from one certain field are involved, the result will most likely be a system that can be used by no one other than these experts. This is, most probably, a consequence of their fixation on their own field of interest. At the other end of the scale, there are the administrators and other (in this context) non-qualified persons that do not have the required experience concerning the devices. When they attempt to construct nomenclatures it gives a similar result, it cannot be used by others than those who made it, but usually, such nomenclatures are of limited use anyway. Our conclusion in this matter is clear, the ideal nomenclature designers must possess, at least, some of these qualities:

- All-round experienced clinical engineer with expert knowledge in several fields.
- At least 10 years experience as maintenance clinical engineer.
- Experienced MEMS user, well acquainted with data systems.
- Wide experience and knowledge of the process of registering medical equipment.
- Acquaintance with administrative routines connected to purchasing, events reporting, etc.
- A certain acquaintance of anatomy.
- The ability to express oneself in writing.

These qualifications of course only apply to nomenclature designers for the Medical Equipment category, but similar qualifications are required for the other categories.

> The practical, everyday running/usage/maintenance of whatever devices or products must be brought to forefront when developing or evaluating a nomenclature. It should also be obvious that any good, useable nomenclature must be constructed and updated through a set of well founded predefined guidelines.

Why design a new nomenclature

In a world where there exists an abundance of nomenclatures for the health sector alone; many of them operative and implemented in user systems, it seems indeed an odd question to ask: "*Why do we need yet another nomenclature?*". It is though a fact, that, in whatever circles we have engaged ourselves in discussions about this matter, there is a general consensus of discontentment to be found about the failings of these nomenclatures. We have found that there are two main parties involved, those who willingly admit that they are not happy and would warmly welcome something better, and there are those who wish to defend the nomenclature that they are using or promoting for obscure reasons of their own. The simple truth is that there is no workable nomenclature and classification system that functions across the borders to the "real world", and certainly none that can cope with the

total involvements around the life cycle of a device. We are well aware of the fact that it is unethical practice to undermine other systems by pointing out their deficiencies in order to promote ones own ideas, and we thought it perhaps rather unwise to do so. We have, however, been encouraged by others to say something along these lines in an attempt to put a lid on the time consuming process of evaluating existing nomenclatures. In order not to pass judgement on specific nomenclatures which would create undue offence, we will suffice to give a generalised picture, explaining why it is necessary to develop a new common European nomenclature.

The requirements embedded in the MDD demands requirements of accuracy hitherto unparalleled. We here face a challenge were we really must think afresh, and the dogma that the nomenclature alone will solve the problems *must be abandoned*. We will therefore like to discuss some important issues lacking support in many of the existing nomenclatures:

1) Specificity

Nomenclatures devoid of a matching Device Type level tries to compensate for this by introducing very specific terms. This, as discussed above, invariably leads to nomenclature that, when used, instead of being very specific becomes both imprecise and cumbersome. To obtain the necessary specificity (as required by the different users/uses) the Device Type level has to be added, and it has to be used in conjunction with the nomenclature (see Chapter 7). Our bold statement is that no nomenclature can find wide application unless the Device Type level is added, and kept continuously updated.

2) Lack of guidelines

Of all the nomenclatures that we have studied, none appears to have the necessary structure, and certainly none have been supplied with guidelines explaining the method by which they are built up. Since the process of making a nomenclature is by no means a static job, it is essential that guidelines should be laid down, whereby continuity can be secured.

3) Consistent terminology

An absolute essential part is the establishment of a terminology concisely describing the terms used throughout the system such as; Category, Device Group, Device Type, etc. This will be the system dictionary and it must be adhered to.

4) User-friendliness

The majority of nomenclatures require a high degree of user knowledge over a vast array of products. No one we have met so far has command over the entire range. Any new nomenclature must be user-friendly. By this we mean that it must be constructed for all kinds of users where the expected extent of knowledge of medical devices/technology/anatomy can span from novice to expert levels. The terminology used in the nomenclature denoting the

terms should be constructed with this in mind and supported by a prolific, but not over accentuated, use of synonyms.

5) User support

As far as we are aware, only the NKKN nomenclature provides an explanation to the preferred terms. All preferred terms should be supplied with at least one, but preferably two, levels of explanatory information. The first supplied should give a laymans description of the term. The second should be available for retrieval on request, giving an expert level description.

6) Significant coding

Many coding systems still insist upon clinging to a significant code number in combination with the term. All previous experience has shown that a significant code will always have a limited number of possible choices which will, sooner or later, become insufficient—unless, of course, it is used to code static data sets. Anyway, significant coding dates back to the times when selection was performed on punched cards, utilising needles set up in a certain pattern to get the matching data.

An old tradition has been to subdivide the nomenclature into block divisions by significant coding schemes such as; technological, anatomical, area of use or other such assimilative properties. The user would then first have to know in which block he/she must search before continuing deeper into the correct subdivision. This method is very often time consuming and provides no real advantages. NKKN suggest that the nomenclature is to be presented in direct alphabetical order, using the terms itself to create blocks of similar devices only when this is clearly advantageous to the user.

7) Categories

To serve its purpose in use we have found it important to divide the nomenclature into a small number of categories which reflects the different professions usage of it. It will then be easier for them; clinical engineers, staff supporting handicap services, etc., to localise "their" terms in the nomenclature (improved "signal-to-noise" ratio).

8) Lack of synonyms

A surprising number of nomenclatures are devoid of, or lacking, a supportive synonym system whereby the user is automatically directed to the correct preferred term. This is essential in a good nomenclature, and of even greater importance when applied to e.g. a MEMS. In the worst cases we have seen synonyms used in a manner giving a "loop effect", meaning the user is referred from one synonym to one or more alternative terms or other synonyms, which then leads back to the starting point.

Remarks

At a meeting held in Oslo in March 1994, our attention was brought to an aspect of classification that we had, until then, not even considered. The CPA (Classification of Products by Activity), CPC (Central Product Classification) and CPV (Community Procurement Vocabulary) are all part of the document *Proposal for a Council Regulation (EEC) on the statistical classification of products by activity in the European Economic Community* (93/C12/01). This system is in its essence targeted towards the monitoring of the flow of commodities and services throughout the internal market assisting in the collection, transmission and publication of national and Community statistics so that undertakings, financial institutions, governments and all other operators in the single market can be provided with reliable and comparable statistical data.

For the purposes discussed in this book we cannot perceive in any way, that this classification system can at all influence upon the requirements for creating a new European nomenclature and classification system for devices. As we have only been presented with an extract of the CPA/CPV system (ref. *IT-plan for forvaltningen.*[16]) we are unable to study its full scope, but presume that there must be "Fields of application" for ME and such. In article 3 within the document *Proposal for a Council Regulation...* there is an opening for the introduction of classifications which are more detailed than the CPA—but this must consist of subdivisions which are wholly contained within CPA subcategories.

There will most certainly be conflicting interests between an extremely generalised classification system for statistic data purposes and a new system to support the MDD[1], where specificity and unambiguity are of all importance, and no doubt some work will be required to harmonise them.

We have also carefully studied the report *Medical Device Coding, A Short Review* [15] that was done at the request of the Medical Device Directorate, UK, and noted the conclusions given there.

In short, our opinion is still the same, there is a need for a new system that must get to grips with all the problems simultaneously. Thinking that a nomenclature alone can achieve the task set before us is like believing that Santa Claus really does come down the chimney.

Device Group register (nomenclature)

Introduction

During the development of our classification system, it became evident that it would be extremely difficult, if not impossible, to construct a totally "watertight" structure. There are simply too many issues to consider to achieve this. Even so, it became obvious that a set of rules or guidelines had to be established, and subsequently adhered to, for the construction and maintenance of the system.

In some instances it was, and still is, necessary to deviate from these guidelines as it proved impossible to create guidelines that solved all the complications that arose during this work. This indeed is one of the main ideas incorporated into the structure: To make a set of guidelines that can be broken if common sense and experience ought to prevail, in other words, it can be both sensible and useful to break them.

Unless one is familiar with the guidelines behind the structure, there is reason to believe that one cannot fully appreciate the ideas presented here. It is therefore deemed necessary that users should get acquainted with the rules for, and philosophy behind, the structure. At the same time it is reasonable to assume that a set of too rigid rules would only promote a nomenclature system that would not be compatible with a practical daily usage. A lot of emphasis has been put upon the required level of knowledge a potential user would be expected to possess about medical devices, and their application, in order to be able to use the system. It was found, during a trial period, that beginners with a minimum of knowledge could easily find their own way through the list of Device Group terms without any difficulties.

This nomenclature system has been developed by hospital personnel—all of whom have both long and broad professional experience, and of course long traditions in registration of medical devices in computerised MEMS. This is indeed a very important factor in creating a useful product—namely, that the users experience and practical needs are taken into consideration during the development process.

In the following description of the nomenclature system's structure, a series of examples clearly illustrate that a well founded philosophy is essential in order to create a classification system that is compatible with practical applications.

The NKKN nomenclature is based on the proposed standard[19], included in Appendix A, and the following definitions and rules apply:

Device Group data definition

Code:	32 bit integer, currently represented using five digits.
Term or name:	Alphanumeric, max. 60 positions.
Description:	Alphanumeric, max. 350 positions (5 lines á 70 positions).
Reference code:	If <> 0 then this Device Group entry is synonymous with the Device Group which code equals this Device Group's reference code (recursive relation).
Template:	Integer, if > 0 then this Device Group is a template.

Table 5: Device Group data definition.

Device Group

A Device Group is a nomenclature term, representing a set of Device Types, usually performing similar or equivalent functions.

A Device Group includes all Device Types, which, among the users of the Device Group terms (professionals), there is general agreement should be grouped together because of:

- regulations and standards
- service-, functional and methodical reasons
- or for other practical, financial or professional reasons.

The Device Groups terms, templates, synonyms and descriptions are formed by expert groups, designated a numeric code, and are confirmed by NKKN.

Coding and the code

The Device Group code is an integer of minimum 32 bits. This is currently represented as a 5 digit number >= 10000. Numbers from 1 to 9999 can be used for the registration of Device Groups specific to local needs, like in-house built devices, or proposals for new Device Groups. The code *zero* or *nil* may have a special meaning, such as defining an unknown Device Group.

The code contains no information whatsoever, except for local codes as outlined above, and is a non-significant incremental sequential code. A new code is generated by incrementing the previously assigned code value by 1. The code has no error detection check characters since human involvement is not intended in the use of the code.

Guidelines

Hierarchical structure

The nomenclature is built up on a hierarchical basis, one could say, a military manner of thinking: One must first identify the object by giving it a designation that tells us what it is, and then one can give a more specific identification by supplementing further details in the following subdivisions. The first level in this hierarchical structure is the most important as this will provide the necessary information that defines the object unambiguously. This then is the main philosophy behind the guidelines.

Example of the hierarchical subdivision:

Boots, male brown - not *Brown male boots*
Trousers, large green - not *Large green trousers*
Analyser, calcium - not *Calcium analyser*
Laser, argon - not *Argon laser*

As mentioned in the introduction to this chapter there can be times and instances when there is a need to deviate from the guidelines, even that of the hierarchical structure. An example of this can be illustrated by the word *apparatus*, which should not be placed before the description of the device's use, something that really would have been correct if one followed the hierarchical structure, e.g. **Apparatus, pertubation** instead of **Pertubation apparatus**. Should one have followed the prevailing guidelines the first example would have been correct, but not necessarily sensible nor practical. All Device Group terms with the word *apparatus* incorporated into its designation would then be listed under **Apparatus, ...**, and this would have been as practical as making a register of companies where suffixes like *Ltd.* or *Inc.* were registered first, thus giving *Ltd. <company name>*. Here then, one must decide between what is correct, according to the prevailing guidelines and what is the best practical solution.

Another example that illustrates such a deviation is shown by using the designation **Oxygen tent**. The correct hierarchical designation would have been **Tent, oxygen**, but how many types of tents are found in a hospital? It seems far more natural to use this word in its every-day form. If on the other hand there had been many different kinds of tents to choose between, then it would have been correct to follow the hierarchical subdivision rule.
This is the case with, for example; **Baths**, which are to be found in many varieties:

Foot bath
Ultrasonic bath
Water bath
Wax bath

Here it is clear that it will simplify the search process through the Device Group list when baths are listed hierarchically:

Bath, foot
Bath, ultrasonic
Bath, water
Bath, wax

Thereby there is only one natural starting point that limits the search for all kinds of baths. To find a *foot bath* one would look up **Bath**, and thereby reducing the search to a minimum. Those not mentally prepared for this form of presentation might think this looks unorthodox and unacceptable, but whenever a new type of bath is introduced that one does not know the full designation of, one can in any event look up under the first hierarchical level **Bath**.

Device Group templates

This is a collective designation for terms which only purpose is to guide the user to an expanded list of preferred terms.

Each template ends with the word **<specify>**, to show that one must choose one of the following Device Group terms from the expanded group. It is not permitted to link Device Types to a Device Group template.

Note! The current version of the recommended data model[19] does *not* support template handling. A revised version of the data model adds a new field to the Device Group register in order to achieve template support in a data systems utilising this register.

Examples of templates:

Bath, <specify>
Bath, foot
Bath, ultrasonic
Bath, ...

Table, <specify>
Table, operation orthopaedic
Table, operation gynaecology
Table, ...

The *description* of a template is general and covers the whole expanded group, and may describe both method, function and/or clinical use.

The use of templates

When there are many different kinds of devices that are used within the same clinical field, utilising the same method/principle or intended for a similar clinical purpose, these can be grouped under a template. Additionally, if there are devices that have little known/used Device Group terms, they may also be so grouped. The purpose of this is to simplify the search facilities in the form of an expanded list.

Example of the use of templates:

a) Same clinical field.

X-ray, <specify>
- **X-ray, film developing machine**
- **X-ray, generator**
- **X-ray, support ceiling**

This example shows devices of different construction and function, but which are used in the same clinical field, and therefore grouped together under **X-ray, <specify>**.

b) Same method/clinical use.

Laser, <specify>
- **Laser, argon**
- **Laser, carbon dioxide**
- **Laser, diode**

Here different kinds of lasers are grouped together under the template **Laser, <specify>**. Even though they are used in many different clinical fields, they all function along the same principal (method).

Sphygmomanometer, <specify>
- **Sphygmomanometer, aneroid**
- **Sphygmomanometer, electronic**
- **Sphygmomanometer, mercury**

Grouped using the template, **Sphygmomanometer, <specify>**, all the devices used for measuring blood pressure will be found. They are all used for the same objective, but this is achieved through the use of different measuring methods.

c) Devices of a special character.

Devices classified by using uncommon or very specialised terms have also been grouped using a template:

Ophthalmo, <specify>
Ophthalmo, adaptometer
Ophthalmo, accommodometer
Ophthalmo, anomaloscope

From our experience, we know that it is very difficult to gain a complete insight into a nomenclature system, and that it is hard to memorise device terms for devices of an unusual or special character. It would therefore be fair to assume that such terms would be elusive to find if they were scattered around in the nomenclature. As an example of this problem we have focused upon devices that are to be found in the clinic for Ophthalmology, and which often are named by uncommon terms. By grouping these in under **Ophthalmo, <specify>**, the search is significantly simplified by having the collective group placed under this *one* template. However, the original terms are of course introduced as synonyms to guide users familiar with such devices, or unfamiliar with the system, to the preferred term.

Ambiguity

A designation must always be precise and without ambiguity. Therefore, the use of words such as; *other*, *diverse*, *accessory*, etc. introduced as the last level of the term is strictly forbidden.

Synonyms

In order to make it easy to search in a list of terms, a liberal number of synonyms has been introduced that lead to the preferred term. Any number of synonyms can be linked to a preferred term. It is not, however, permitted to link a Device Type to a synonym. A synonym can lead directly to a preferred term, or alternatively to a template if there exists several possibilities of choice. If the latter is the case, the user must choose from the expanded list of terms given under the template.

Examples of the use of synonyms:

ACT-meter - see **Analyser, coagulation**

Here the synonym leads directly to the correct Device Group term.

Nebuliser - see **Humidifier, <specify>**

Here the synonym leads to a template, and the expanded list of terms is then used to pick the required term:

Humidifier, <specify>
Humidifier, ordinary
Humidifier, nebuliser
Humidifier, ultrasonic

Descriptions

Each Device Group term in the list is supplemented with a description that describes the device, what it is used for, or how it works. A description often begins with one of the words; *Apparatus*, *Unit*, *Instrument* or *Equipment*. These terms are defined as follows:

Apparatus	A device which executes the function it is intended for, independent of other devices.
Unit	A device that must be coupled to another device to execute the intended function.
Instrument	Surgical handtools and instruments of a mechanical nature (can be power driven). Can also be applied to electronic measuring instruments.
Equipment	General definition for one or several devices including the necessary accessories to execute the intended function.

Popular terms

In many cases "popular" terms for medical devices are used by hospital staff, and where these have been found to be suitable, they have been retained and incorporated into the nomenclature system.

Example of a "popular" term:

Pulse Oximeter

A pulseoximeter is in reality a photometer, and should therefore, remembering the hierarchical structure, have been given the following designation: **Analyser, photometer oxygen**. This would however be inappropriate on a daily user basis and at the same time, **Pulse Oximeter** seems the right term for the job.

Trade or brand names

The use of trade or brand names as preferred terms is not allowed. The reason for this is to avoid terms that in a purchase situation will favour a particular manufacturer's or supplier's product. The trade name by which the device may be marketed could coincidentally be identical with a term in the nomenclature, and therefore giving this product a leading edge over others.

However, because some trade or brand names are embodied in the jargon used by hospital staff, they have been introduced as synonyms.

Example of trade or brand names used as synonyms leading to the preferred Device Group term:

Dinamap	synonym for **Sphygmomanometer, electronic**
Propaq	synonym for **Monitoring, transportable**
Coulter counter	synonym for **Analyser, haemotology**

National language spelling

A natural part of developing the NKKN nomenclature is the effort put into keeping the final product as uniform to the Norwegian language as possible and to avoid the inducement of foreign language.

Examples of the Norwegian language and spelling:

English		Norwegian	Comment
Photometer	becomes	**Fotometer**	"*Ph*" is replaced by "*f*" in modern Norwegian language.
Endoscope	becomes	**Endoskop**	"*C*" is almost always replaced by "*k*" in Norwegian language. The "*e*" at the end of "...*scope*" is dropped.
Cardio	becomes	**Kardio**	Same as above.

Even so, it was again considered correct to deviate from the rule as shown in the following example:

CT, that stands for *Computer Tomograph* is such a familiar term, that to translate this to Norwegian (DT = Datatomograf) would not make any sense. *CT* has been readily accepted into the nomenclature system as it is.

It is strongly advised that all national nomenclature systems should be translated in such a manner as hence prescribed.

Alphabetic order

All the Device Group terms and synonyms are listed in alphabetic order so that the user can quickly thumb his/her way through the contents of the nomenclature.

Maintenance of the NKKN nomenclature

The NKKN nomenclature is updated regularly by three expert groups, each consisting of three members, and encompasses the following ME subdivided into:

- Electro-medical appliances and surgical/anaesthesia fields.
- X-ray and other picture reproduction devices and radiation therapy.
- Laboratory devices.

The nomenclature users are encouraged to propose new terms and synonyms. All proposals for new terms and synonyms is to be approved by the responsible expert group before they are added to the nomenclature. The NKKN project team is responsible for updating the nomenclature database, and the QA/QC of its contents.

Device Type register

Introduction

It might be said, at first glance, to be an easy task to formulate some guidelines for the identification of a *Device Type* in a manner which would provide us with an absolute guarantee for traceability in a database. Unfortunately, we have to concede that this is not so, and to make a set of guidelines that are one hundred percent infallible is simply impossible within the framework of today's situation. This is a fact that we must resign ourselves to. However, we would like to anticipate that it is quite possible to make guidelines that will provide something like a ninety percent coverage of the variety of type designations to be found.

The problem has its origins in the freedom that manufacturers of medical equipment have so far enjoyed when it comes to the labelling of their products proffered onto the market. There does actually exist some requirements for the marking/labelling of devices (they will be discussed later), but they are very unspecific—and can be interpreted as so desired. This situation has given rise to the quite chaotic marking of devices that at times can be extremely confusing to comprehend, even for expert clinical engineers. This is the reason why the information, supplied upon the equipment and converted to data, is of variable use when compared to what is demanded for identification of a Device Type, as prescribed in the NKKN Steering Committee's report for the data model (ref. Appendix A).

Our view of this fundamental problem is that it has be divided into two phases; *the present time* and *the future*. The present time is reckoned from today, where we are subjected to live with these unsatisfactory conditions, and a time period lasting until at least 1.1.1995 when the MDD[1] will be enforced. This date marks the beginning of the future, where we dare anticipate the development and implementation of a regulatory norm for the labelling and identification of medical devices proffered onto the EC and EFTA market.

The NKKN project team has therefore made a specification based upon practical experience, gained through their ongoing work, concerning the collection and build-up of Device Type data in a database located at HUH. This incidentally forms the basis of the NKKN's national Device Type register. This specification was a part of a proposal[6] presented to CEN/BTS3.

Device Type data definition (Most significant fields)

Code:	32 bit integer, currently presented as five digits.
DG Code:	32 bit integer, reference to Device Group.
Make:	Alphanumeric, max. 60 positions.
Model:	Alphanumeric, max. 60 positions.
Trade name:	Alphanumeric, max. 60 positions.
Family:	Alphanumeric, max. 60 positions (new proposal).

Table 6: Device Type data definition.

Device Type

A Device Type is identified by its *Make (manufacture or brand)* and *Model designation*, is coded and linked uniquely to one Device Group.

It is actually by implementing the Device Type level that the specificity required by the MDVS can be achieved, and *not*, as many experts seem to believe, through the nomenclature alone. This level, coupled together with a new European standard for device labelling, should provide an infallible system throughout the market when it is established.

The label

Every device shall bear identification.[1,5,17] We consider the data supplied on the device's label as the basis for identification of a device, and hence this data should be of such a quality that it can be used for the communication of information between data systems.

The label is usually located at the rear side of the device, but sometimes it can be found underneath. It can also be a part of a device's body shell or housing and found in printed, cast or embossed form. There are endless variants of what may be called labels, supplying a vast variation of accessibility, readability and information content. This situation will continue until a common European mandatory regulation, expressing what kind of information is to be displayed upon the label, are formulated and enforced.

The existing requirements for labelling

A) Medical Devices Directive (MDD)[1]

In annex 1, the following requirements for device labelling can be found:

"13.3 The label must bear the following particulars:
a) the name or trade name and address of the manufacturer. For devices..."

"b) the details strictly necessary for the user to identify the device and the contents of the packaging."

Comment:

What is "strictly necessary" (b) is not at all specified. The requirements/rules that we have prepared clearly indicates what is "strictly necessary", and will make it quite possible to identify a product unambiguously. (a) is more in accordance with our specification inasmuch as the *Name* or *Trade name* is to be supplied, but is still an inadequate requirement.

B) prEN 46002[17]

In the prEN 46002 the following is mentioned about identification (Labels and Labelling):

"3.10 Label

All written, printed or graphic matter

a) on a medical device or any of its containers or wrappers or
b) accompanying a medical device

relating to identification, technical description and use of the medical device but excluding shipping documents."

"3.16 Labelling

The process of combining labels (see 3.10) with medical devices."

Comment:

The most specific suggestion about the identification of medical devices mentioned in this standard is, "...relating to identification, ..." but, what is meant by "...relating to identification, ..."? These definitions do not contain any clear indication of how or by what method unambiguous identification of a Device Type can be accomplished. In other words, they are useless for our purpose.

C) IEC 601-1/EN 60601-1[5]

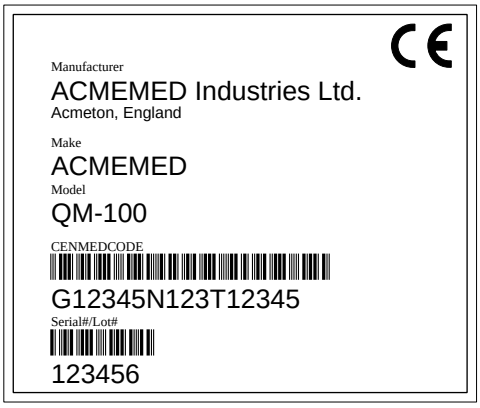
In the IEC 601-1, the following is commented about the identification of the device type:

"*2.12.2 MODEL OR TYPE REFERENCE (type number)
Combination of figures, letters or both used to identify a particular model of EQUIPMENT."

Comment:

This definition is completely useless when applied to the identification of a Device Type. This can be interpreted such, that the possibility to combine which ever number and letter combination exhibited upon the device, is open. There is little sense in suggesting that number/letter combinations define the Device Type. It has to be made very clear *which* number/letter combinations which are to be incorporated within the definition.

The label's design and location—some ideas for a "standardised" CE-label



Generally speaking, it can be said that the Device Type label shall be made of a durable material that will sustain washing with strong disinfectants, can be sterilised (temperatures up to 160 °C), and is located for easy accessibility. It shall be marked with an easily read, durable inscription and affixed to the device in a manner that ensures removal difficult without the use of tools or excessive force.[5]

The lettering shall be easily read. The use of characters from alphabets other than ISO/Latin1 shall not be permitted, this to avoid problems when transferring data between different data systems. The label must be easily accessible for the user when possible, and should be displayed in such a manner that inspection can be carried out without any part of the device being dismantled. Generally speaking, it appears to be that manufacturers, no matter what they manufacture, wish to *hide* the label. It is sometimes very tiresome to register equipment after it is installed because one has to physically move or dismantle equipment in order to read the label.

Recommendation for Device Type identification

The use of bar coding or OCR (Optical Character Recognition) for identification of products is a very common method for ensuring information exchange in an easy and secure way. In the retail business of today, a vast multitude of products are unambiguously identified using bar coding. Such a system must be, without doubt, of great value within the health sector, and we cannot see any reasons that should hinder the introduction of this method.

Requirements for unambiguous identification of a Device Type

As earlier mentioned, it is of little use—in fact no use at all—to say that number/letter combinations can define a Device Type. It must be made absolutely clear which number/letter combinations are the ones that will provide us with the correct designation and from where these are to be taken.

We have therefore found it necessary to stipulate requirements for which data that is required, in order to create an unambiguous Device Type record in the database:

- *Make* − see 1) under *Rules for definition of a Device*.
- *Model* − see 2) under *Rules for definition of a Device Type*.
- The codification of the Device Type using a numeric code.

The two data elements, *Make* and *Model* stringed together, shall provide the unambiguous identification that is of a suitable quality for human perception. In addition the Device Type is coded using a numeric code to be used as the referential data element in computerised data systems. The way of adding the code are elaborated in *ISO/IEC JTC 1/SC14*.[18]

Make and *Model* are, in the majority of cases, collected from the label. However, there are devices to be found where this is not possible, and what is to be done in such instances will be discussed later.

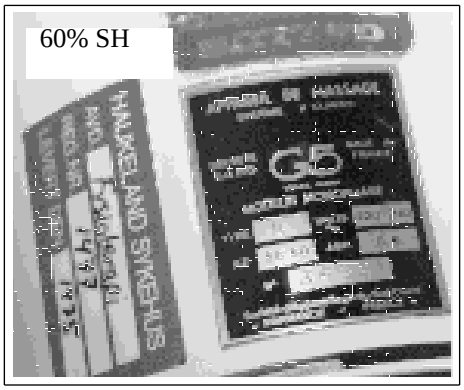
The allocation of codes

Each manufacturer can be allocated a range of codes for coding purposes. This could be done in a similar manner as ISBN numbers are distributed to publishers. This system functions in such a way that the individual publisher is supplied with a number series, and when a book is published it is equipped with the next vacant number from the series. The publishers themselves manage this system. Implementing such a system in the field of medical devices would mean that a manufacturer that has a large product line, would be allocated a large number series, whilst one that produces only a few items, would receive a small series. Again the manufacturer would perform the coding themselves.

Labelling, the conclusion

The said documents do not provide a good enough foundation for the definition the data elements that make up a Device Type, this simply because a data system is totally dependant upon unambiguous data in order to give meaningful information out. Also, if the quality requirements for the data to be registered are inadequate there will always arise a possibility for the introduction of interpretations. This will soon lead to an unuseable database, even though the system might be soundly constructed.

Even so, we believe that MDD[1] (ref. § 13.3 (b)) gives us the opportunity to define what is essential precisely because it is so vague (it only stipulates *strictly necessary*) about labelling requirements. In retrospect, the other standards suggests general requirements that are unuseable for such an important matter.



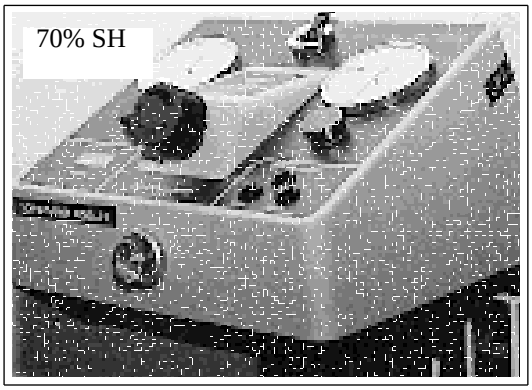


Figure 9 *Figure 10*

Two examples of the kind of difficulties that can be met are illustrated above. Figure 9 shows the type/model label on a massage apparatus of French origin bearing confusing information regarding its make, is it *H.Cunier*, *Breveté* or *Marmande*? The model K and trade mark G5, both exhibited on the same label, is also a source of confusion. Figure 10 shows a tourniquet apparatus of completely new design manufactured by *Speidel & Keller*, which surprisingly enough was completely devoid of any type/model label at all. This problem requires acute attention, and will be one of the foremost tasks to be resolved if data exchange is at all to be achieved.

The work currently undertaken by CEN TC257 and CEN TC257/SC1 will hopefully end up as standards that satisfy the requirements for the future, when computers will play an ever increasing role in the marketplace (of medical devices). In fact, the current chaotic state of affairs do provide us with the unique opportunity of making good standards that, we believe, will fulfil the requirements of all "players" in the market.

The future (Norwegian approach)

In co-operation with the authorities, the suppliers associations and a data distributor, we are planning to establish a national database containing all ME placed on the market in Norway. This is meant to be a voluntary arrangement where the suppliers will be given the possibility to present their own product information in addition to the basic data set. Databases already exist for single-use devices, and by interconnecting the databases—and by making them accessible to purchasers and health care planners—we hope our approach will be successful. However, if this scheme does not succeed, the authorities will consider new measures for the establishment of the database.

The existing register of already available Device Types, and future Device Types provided with CE-certification will be registered in this national database.

The future (a proposal for a European approach)

Hopefully, the current activities within CEN and CEC will result in new standards which eventually will lead to easy and unambiguous identification of devices. In addition we would like to see the establishment of a centralised database containing the nomenclature and all Device Types registered with relevant data. This database should be freely available to all interested/involved parties, maybe through a subscription scheme to fund it. It may be possible to establish this database as a core for the MDVS, or it may be taken care of by some manufacturers association. The manufactures or their European subsidiary should be obliged to register all their products in this database, regardless of risk class, in order to obtain the level of identification which is *strictly necessary* for all users. This will then lead to a system that provides all "players" in the market; manufacturers, suppliers, authorities, purchasers and end users with a common classification system that in the long run will be beneficial to all.

The present time (Norwegian approach)

In co-operation with other hospitals in Norway we are now registering Device Types by collecting the actual Make, Model, Trade name and Family from the labels or text printed on the devices. We do not accept Device Type designations collected from any written sources, without these designations being visually checked against the actual device label. This is very meticulous work, and it is often difficult to differentiate between data like the Model and Trade name on older devices. To achieve the highest possible quality from this work, preliminary guidelines have been made. These guidelines give instructions for how to interpret the labelling in order to get the correct data registered, and also discusses many issues related to problems which may be encountered during the collection of Device Type data. At present the Device Type is coded by NKKN using an non-significant numeric code in the range 10000 to 99999.

Close-up photos of the front and rear (with type/model label) of the devices are used in special cases to document the work. A list of each (Norwegian) supplier's Device Types will be presented to the supplier for comments and final acceptance. Each Device Type is also linked to the appropriate Device Group before the register is distributed to the users.

Rules for the registration of Device Types (present situation)

These rules applies to all existing devices and all devices not affected by the awaited mandatory standards from CEN.

Our experience has clearly shown that correct Device Type designations *cannot be collected from sales brochures, literature or similar sources*. We are of the unequivocal opinion that the only method that can produce reliable data is through the visual inspection of the device label, and from it collect the required data using predetermined rules. Photographs of the label and the device itself may prove to be a useful way to document the chosen designation. This kind of work demands the highest degree of accuracy from the

involved personnel—and we believe it is of great importance that they have the necessary understanding of the requirements, and that they use the guidelines as prescribed. Unless these criteria are fulfilled, we can simply forget the idea of information exchange, whether this should be for internal use within the hospital, or between hospitals and other parties both nationally and in other countries.

1) Make

Alpha-numeric company brand name (not figurative (means something), or non-figurative (means nothing) logo) which can often be identical with the manufacturer's name, or its acronym.

Example:

Manufacturer	**Make**	**Acronym**
General Motors	Opel	
Ford Motor Co.	Ford	
Hewlett Packard Co.	Hewlett Packard	**HP**
J. Bibby Science Products S.A.	Bibby	
Hayashi Denki Co., Ltd.	Hadeco	**HADECO**

When establishing the *Make*, all prefixes, suffixes and abbreviations expressing the company ownership form shall be removed, such as; Co., Ltd., Inc., etc. The *Make* is usually written with its first letter as a capital letter. If the *Make* is abbreviated with substituting capital letters (not an acronym), then it is entered in capital letters as prescribed above with the full name entered behind this in brackets, e.g. *ABB (Asea Brown Boveri)*. Characters not available in the ISO/Latin1 character set are ignored.

2) Model

The Model is depicted upon the label as the device's *Type* or *Model* designation. Should both Type and Model be displayed on a label, then these two designations shall be registered consecutively, separated by a space, and with Type as the first element.
In some cases, a revision or version number may be displayed as extra information after the model designation, or on a separate label for such. This is not to be included as part of the model designation. On the devices' labels the guide text for the model designation can be expressed in a variety of ways, such as:

```
Typ, Type, Model, Modell, I.D.Nº, E-Nr., Mod.No.,
Part No., Cat.No.
```

In cases where dubious labelling creates any doubt about the model designation then the service manual or supplier/manufacturer may provide the necessary information required to settle the matter. In the event of further discrepancies, the decision about the model

designation for products available on the Norwegian market will be taken by the NKKN project team, and will be presented to the supplier/manufacturer for approval.

The model data is entered exactly as it is reproduced upon the label and it is necessary to secure absolutely all characters—spaces, full stops, commas, slashes, dashes and other special punctuation. Capital letters are used exactly as displayed. However, characters not available in the ISO/Latin1 character set are ignored.

3) Trade name

The *Trade name* is often synonymous with the "popular" sales name, and is often found printed upon the device's front.

Example:

Make	**Model**	**Trade name**
Abbott	F738-36	OXIMETRIX 3 Printer
Ivac	2080A	Temp-Puls II
Mediada	5570	OXYGEN MONITOR
Richard Wolf	2280.001	Riwolith 2280

4) Family

The *Family* is the name of a complete product line or range of medical devices that belongs naturally together. This can be expressed as: The devices cover a particular diagnostic/ treatment function or they may be technically related, and the manufacturer wishes to present a range of devices to the customers in an uniform way. For example:

Make	**Model**	**Family**
S&W	9040	Athena
S&W	9140	Athena
S&W	9210	Athena
S&W	9215	Athena

The example in figure 11 is found on the rear of a Philips brochure for X-ray equipment (`Multi DIAGNOST 3`). The family name is `DIAGNOST`.

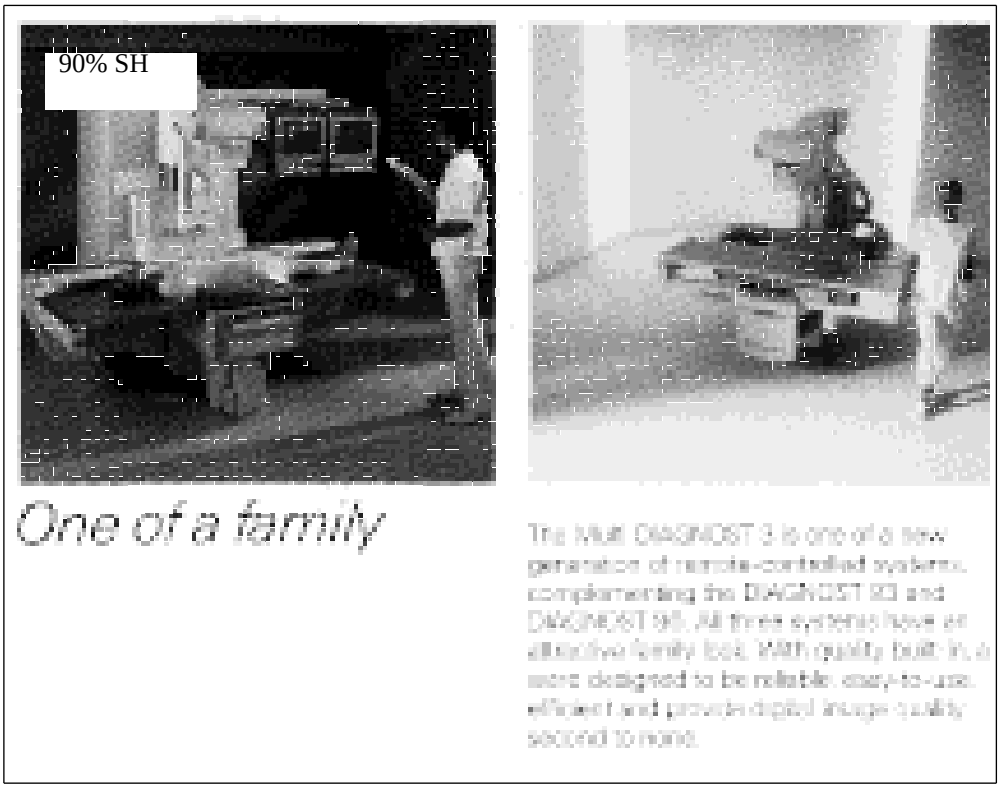


Figure 11: Philips products belonging to the same family (product line).

5) Manufacturer

The *Manufacturer*† is the name of the company that makes the device, or the last party to carry out modification to the device before this is proffered onto the market.

Should abbreviations expressing the company ownership such as; *Plc*, *Ltd*., etc. precede the manufacturer's name then these are to be moved behind the name. The name (or names) first letter is to be written with a capital letter, the rest in lower case lettering, with the exception of the company ownership abbreviations as shown below. All the individual words comprising the full name are to be separated by one space only.

† "manufacturer" means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. MDD[1], Article 1 §(f).

The preferred style for some company ownership abbreviations in various countries:

Belgium	BV
Denmark	AS
Finland	OY
France	CGR
Italy	Spa
Germany	GmbH
Norway	AS
Sweden	AB
Switzerland	AG
The Netherlands	BV
United Kingdom	Ltd.
USA	Corp., Inc.
Multinational	Co., Corp., Inc., Ltd.

Example:

Vingmed AS

Selection of Device Group term

The Device Type is singly related to a selected Device Group term. In Norway only the official NKKN nomenclature is allowed for this purpose.

Code assignment

The next unused code is assigned to the Device Type before it is stored in the database.

Medical Device Categories

Introduction

The medical device nomenclature and device types should be linked to different superior *categories*. The main reason for introducing this new level in the data model is the fact that there exist a number of large and relatively distinct such categories when considering the professional use of the devices. The introduction of this level also serves as an important factor to increase the "signal-to-noise ratio" for the end user who is to navigate in a database system. Remember, there are approximately one million Device Types available/in use on the European market. This level (or axis) should be relatively coarsely divided into no more than ten different main categories for medical devices. Since the original Norwegian datamodel was mainly aimed at the Medical Equipment category, we need to add the category level to make the datamodel useable when considering the MDD's definition of the Medical Device term.

The database system must be constructed in such a manner that makes it possible to cross correlate products that can be found in more than one category, thereby ensuring that only one Device Group is available for that particular group of products, regardless of which category a user may be utilising. For instance, a *Nerve stimulator* can be found in the category for *Medical Equipment* and *Aids for Handicapped and Rehabilitation Devices*.

Category definition (preliminary)

Device Category

A Device Category is a collection of Device Types and/or Device Groups catalogued in accordance with the devices professional use and their properties.

Expanded data model

A proposal for an expanded data model has been made in the form of a new level (category) on top of the original (see page 13) and, in principal, demands no alterations to the existing model or its data definitions.

This proposed solution is based upon a linked list (database) of device categories that are related to the Device Type and Device Group registers in a "many-to-many" relationship. By using a linked list, it is quite possible to build an architecture that can be utilized in anything from a "super system" that would include every conceivable product upon the market, to modest systems that contend with only one category (as we would typically find in a maintenance system for ME). "Many-to-many" relationships are necessary in order to deal with the fact that a Device Group/Device Type can (often?) be localised in several categories. Figure 12 depicts how such a structure may look.

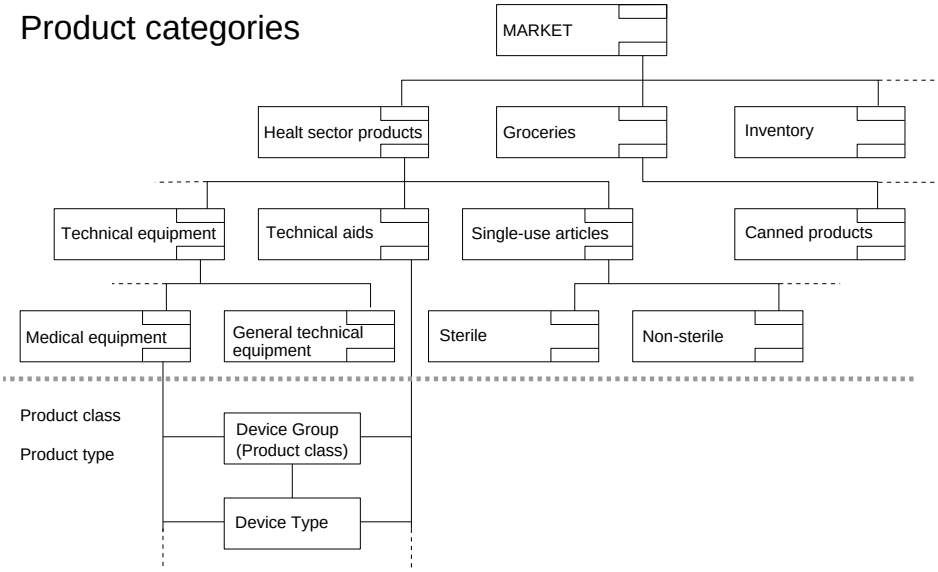


Figure 12: Examples of product categories in the market.

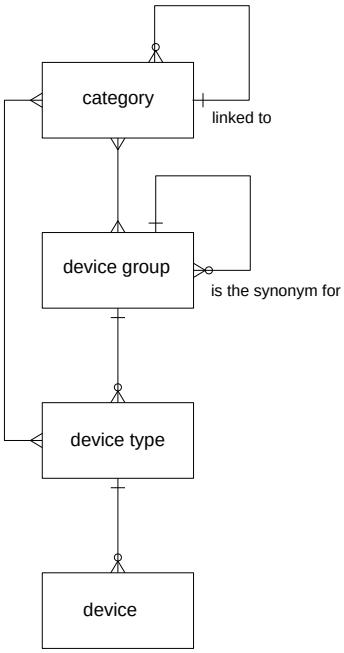


Figure 13: Basic datamodel with Category added.

Suggested Device Category data definition:

Code:	32 bit integer, currently represented using two digits.
Parent code:	32 bit integer, currently represented using two digits. Contains code of its superior category, 0 if main category.
Name:	Alphanumeric, max. 60 positions.

Table 7: Suggested Device Category data definition

Recommended Categories

The National Board of Health has proposed that the health sector procucts on the Norwegian market are to be divided into the Categories as shown in figure 14 below:

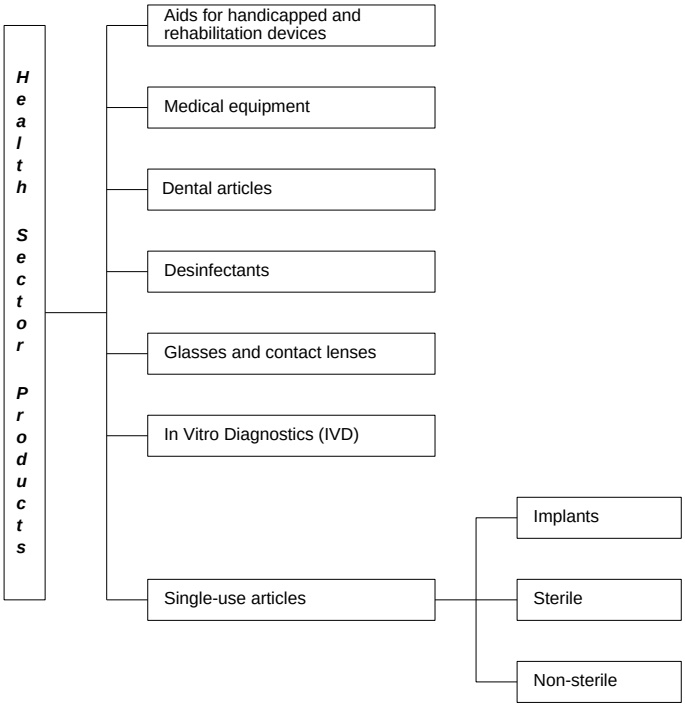


Figure 14: Recommended Categories.

Nomenclatures for the various Categories

The coming Norwegian (and eventually a common European) nomenclature for devices must comprise all the categories listed in figure 14. As the situation stands today, only the nomenclature for the category *Medical Equipment* is available for the intended use (the

NKKN nomenclature for ME). For the other Categories there exists a mixture of nomenclatures or product lists both in Norway and other countries that could be used after certain adoption work had been done. Some of these are lists containing products that the manufacturers/suppliers are obliged to register in official registers run by the authorities before they can be introduced onto the Norwegian market.

We do not consider it at all wise to implement any of the existing nomenclatures to be found, at least in their present state, because none of them are constructed in the prescribed manner making them suitable for the data exchange system that we now see the contours of.

Medical Equipment

As mentioned above, the NKKN nomenclature for medical devices will be used for the category *Medical Equipment*. This is the official Norwegian nomenclature for ME.

Aids for the handicapped and rehabilitation devices

For this category the *ISO 9999 - Technical aids for disabled persons; classification*[20] is already in use (as a nomenclature). This nomenclature can easily be adopted, though with some modifications. The matter is to be discussed with ISO: Technical Committee 173.

Dental articles

In the Nordic countries, NIOM is the responsible authority for the assessment of dental articles. NIOM do not use any kind of nomenclature, they only refer to the ISO standard's number and name applying for the actual product group. The further identification is done by assigning the product name (Model) to the Make, and this is in accordance with the recommended data model.

Disinfectants

As far as we know, there exist no nomenclature for this category, and it is therefore necessary to develop a new, starting from scratch.

Glasses and contact lenses

A national register containing events with glasses and contact lenses is run by the Department of Opthalmology at HUH. The need of a nomenclature is not a matter of urgency, because all the actual products can probably be classified using 3 - 4 Device Groups, and we believe that the implementation of this register can be done in a relative short time.

IVD

We have recently been informed about a French (nomenclature) system for IVD. However, we have not been able to get hold of this system, and therefore do not know anything about it.

Single-use articles

This category consists of a very large number of products, and it is therefore found to be appropriate to split it into three subdivisions:

a) Implants

A national register containing events with hip prostheses is run by the Department of Orthopaedics at HUH. The actual products can be classified using approximately twenty Device Groups. The identification of the the product type is done according to the recommended data model. The implementation of this register can be done in a relative short time.

b) Sterile

In Norway, all sterile products must be controlled and certified by Statens Institutt For Folkehelse (SIFF)—before they can be proffered onto the market. SIFF has developed a nomenclature for this purpose, and the products are identified with a 10-digit code, which in most cases will be unique. The product designation is a combination of the Make and the product name (Model), and this is in accordance with the recommended data model.

c) Non-sterile

There exists several Norwegian product lists for Non-sterile products, but we doubt that any of them can be used as a nomenclature without major changes. The product list published by the suppliers association, Leverandørforeningen For Helsesektoren (LFH), may be considered as a starting point for a nomenclature for Non-sterile products.

Problematic issues

We have, during the development process of the NKKN nomenclature, identified some particular groups of medical equipment which have proved extremely difficult to handle, and we think it important to put some focus upon these. Even though we have already spent a lot of effort trying to solve these problems we feel that the nomenclature can still be enhanced, especially the parts concerning:

- X-ray equipment
- Data hardware and software

X-ray equipment

The main problem, when classifying X-ray equipment, seems to lie in the complexity and diversity of the X-ray laboratory. Most X-ray experts we have engaged in this work, have had the habit of considering all units placed in one X-ray laboratory as more or less one device, and they may name it as; *Angio lab*, *Mammae lab*, *CT lab*, etc. This way of considering X-ray equipment has also been implemented into many existing nomenclatures, where one can find Device Groups like *Angiograpic units*, *Radiographic units*, etc., which in reality is a collection of many devices that should be handled and registered separately, in order to satisfy the requirements for MEMS, vigilance reporting, traceability, Device Type linking, etc.

This is more or less the same story as described in Chapter 5, under the paragraph "*Is the device a composite device which should be considered as several devices covered by more than one term?*", but there are two more problems that occurs in this context:

- The *Installation* syndrome
- The "*Siemens*" syndrome

The Installation syndrome

It has been claimed that a nomenclature cannot be constructed in such a manner so that it could cover the whole scope of X-ray equipment in a complete and reasonable way. Some experts are even insisting that the only solution is to create Device Groups for entire installations, like *Angio lab*, *CT-lab*, etc. The consequence of this line of thoughts will be that we, at the moment, have to register all the devices that make up an X-ray laboratory as one device. We regard this solution to be completely futile, and have clearly stated the reasons for this in Chapter 5 as outlined above.

Although we fully appreciate the need to look at an installation as one object, we insist that this should not be done through the nomenclature, but must be achieved through appropriate data structures in the MEMS. If the data system is constructed in accordance with the recommended data model, it will be quite feasible to register every single device

separately, and then link them together creating the actual installation (the complete X-ray laboratory), which can be named accordingly, as e.g. *CT lab 1*, *MR lab 2*, etc.

Figure 15 (next page) depicts a typical X-ray lab, of course, also containing units that are not regarded as X-ray equipment. Hopefully, this figure illustrates why it cannot be recommend to register the complete installation as one piece (using *one* Device Group): If, for example, the light source were to loosen, fall down and cause injuries to the patient, the *Light source* will be the object for vigilance reporting etc., not the X-ray lab. In the same way, if the patient in some way were to get his fingers jammed in the Examination table, the *Examination table* will be the object of interest, not the X-ray lab (this example is taken from an actual report). This way of considering the different units, will also be appropriate for the event recording in a MEMS: Acutely needed repairs or planned activities can be directed towards a single unit, not only the X-ray lab.

The installation shown in figure 15 can be registered in the installation register and given an appropriate name. This example is taken from the installation register found in the MEMS at HUH, see figure 16. In this figure the various units of the X-ray lab are marked with highlighted reference numbers which are to be found positioned at the left side of the actual equipment list shown below the installation list in figure 16. This list contains the devices that are related to the installation, with the units' registration number, Device Group and Device Type. From this list the devices can be handled singularly or altogether as one piece.

The device marked *NB*! in figure 15 is an ordinary PC used for office routines. It is therefore not regarded as a Medical Device (ref. the paragraph *Data hardware and software* in this chapter), and is not registered in the MEMS.

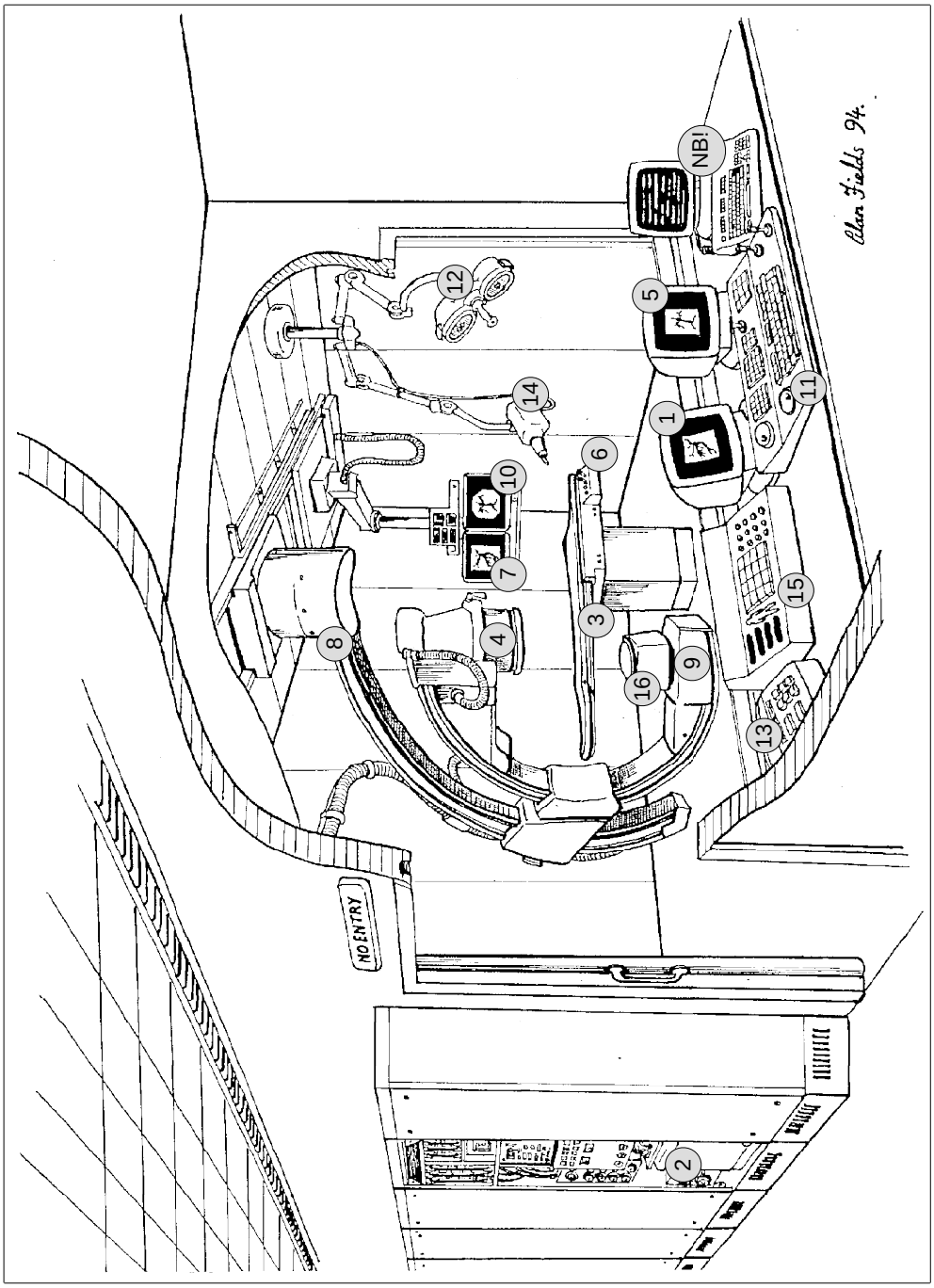


Figure 15: Typical modern X-ray lab, named "X-ray lab 03" in our Installation register.

```
Installation type Stationary

Installation

3 CT lab 01
3 CT lab 02
3 MR lab 01
3 MR lab 02
3 Scintigraph lab 01
3 Scintigraph lab 02
3 X-ray lab 01
3 X-ray lab 02
3 X-ray lab 03
3 X-ray lab 04
3 X-ray lab 05
3 X-ray lab 06
3 X-ray lab 07
3 X-ray lab 08
3 X-ray lab 09
3 X-ray lab 10

E)quipment

X-ray lab 03

1  17403.000 Monitor, monochrome                Siemens 11 63 000 X2077
2  17405.000 X-ray, generator                   Siemens 11 63 737 X2090
3  17406.000 X-ray, table examination           Siemens 90 23 458 G122E
4  17407.000 X-ray, intensifier                 Siemens 84 44 846 G5326
5  17402.000 Monitor, monochrome                Siemens 11 63 000 X2077
6  17397.000 X-ray, operator console            Siemens 61 64 847 G2174
7  17398.000 Monitor, monochrome                Siemens 11 63 018 X2078
8  17400.000 X-ray, stand ceiling               Siemens 28 45 001 G2174
9  17429.000 X-ray, X-ray tube                  Siemens 11 89 901 V2173
10 17399.000 Monitor, monochrome                Siemens 11 63 018 X2078
11 17397.000 X-ray, operator console            Siemens 61 64 840 G2174
12 17394.000 Light, operation                   Heraeus 56067745
13 17392.000 X-ray, contrast media injector cont Medrad RPU
14 17393.000 X-ray, contrast media injector     Medrad H5P
15 17405.001 X-ray, operator console            Siemens 11 10 803 X2094
16 17430.000 X-ray, collimator                  Siemens 28 47 155 G2126
```

Figure 16: Example from the MEMS at HUH, showing the Installation register and the related equipment of the installation "X-ray lab 03".

By choosing the submenu E)quipment (by typing <E> when the cursor is placed on the actual line of the selected installation), which is one of several submenus in the Installation list, all units related to the particular installation will be listed. From the list of equipment the system allows one to treat every unit singularly. The installation can also be handled as one piece of equipment. This allows one, among other things, to generate planned activity jobs for the whole installation or single units related to the installation.

Another alternative that may also bring about the desired result could be the possibility of building up a complete X-ray laboratory by connecting through the Device Types in much the same manner as shown above. We have at the time of writing this book, done little research into this line of thought and can therefore not enlighten upon the possibilities.

Designation of X-ray equipment Device Types (the Siemens syndrome)

In Norway, one of the main X-ray equipment suppliers is the Siemens company. Together with Philips Norge and General Electric (distributed by Medirad AS) these companies provide the majority of the X-ray equipment to be found in Norwegian hospitals.

The designation of Device Types of equipment manufactured by Philips and General Electric can, in most cases, easily be ascertained and registered in a Device Type register. The Device Types of these two makes, are as a rule consisting of a series of numbers. A typical Philips Device Model may be `4522 161 17823` (Trade name `BV 25`, Device Group: **X-ray, mobile fluoroscopic unit**), and a typical General Electric Device Model `46-165600G11` (Trade name: `AMX II`, Device Group: **X-ray, mobile fluoroscopic unit)**. Each unit has only *one* label, so it is quite clear that the label's data applies to the unit it is affixed to.

The Device Types of equipment made by Siemens does not, however, have this strict structure, at least, this is how it appears to the medical engineering staff. The X-ray equipment from Siemens has, in most cases, several labels on each unit, each with a different Device Type number. This causes problems when ascertaining the correct Device Type. A Device Type can only be designated according to the data from one of the labels, and how to find out which one of them is the bearer of the correct data for the actual unit is a serious problem.

A typical Siemens Device Model may be `11 63 737 X2090` (Trade name: `POLYDOROS 80`, Device Group: **X-ray, generator**). According to information from the local Siemens supplier, the model string contains the following (the above mentioned number is used as example): The five last characters (`X2090`), by Siemens called *Type No.*, is a kind of superior Device Type number, which tells something about (we do not know exactly what) what kind of device the actual device really is. The seven first numbers (`11 63 737`), by Siemens called *Part No.*, give the exact version, and the unique identification of the actual Device Type. There is also, after the *Type no.* added a single number which indicates at what Siemens factory the device is produced. This number is only presented in the part list, and is therefore excluded from the Device Type designation.

The described method of how Siemens are putting together the Device Type data can be found on most Siemens equipment, but not all, thereby creating further confusion, but will not be discussed in this context.

Recently, a new `Siemens Multistar D Angio` stand was purchased at HUH. A check list containing all components and their part numbers, was included with this delivery. As far as we understand, this is not common.

In the process of registering the equipment we found, as usual, that the different units of the tripod had several labels. The examination table (Trade name: `Koordinat U`, Device Group: **X-ray, table examination**) was provided with four labels (figure 17). One was

affixed to the underside of the table, two to the table column and another to the table console (mounted on the side of the table). Which was to be chosen as the correct bearer of information for the examination table when ascertaining the Device Type? We assumed that the label attached to the table console was meant to be for the table console, so that particular label was excluded. This assumption was found to be correct, when comparing this to the part list. After some discussion, we decided to choose the label on the underside of the table as being the correct Device Type designation, as we perceived this part to be the *table* in the true sense of the word. But, when this part number was compared to the part list, we could not find this number at all, and the part list's part and type number stated for the `Koordinat U` table, was not be found on the table.

We can assume that this is convenient for the manufacturer. But for the equipment users and maintenance engineers, it remains an enigma, and as for the main theme of this book, namely "unambiguous data exchange", some serious thinking is indeed needed.

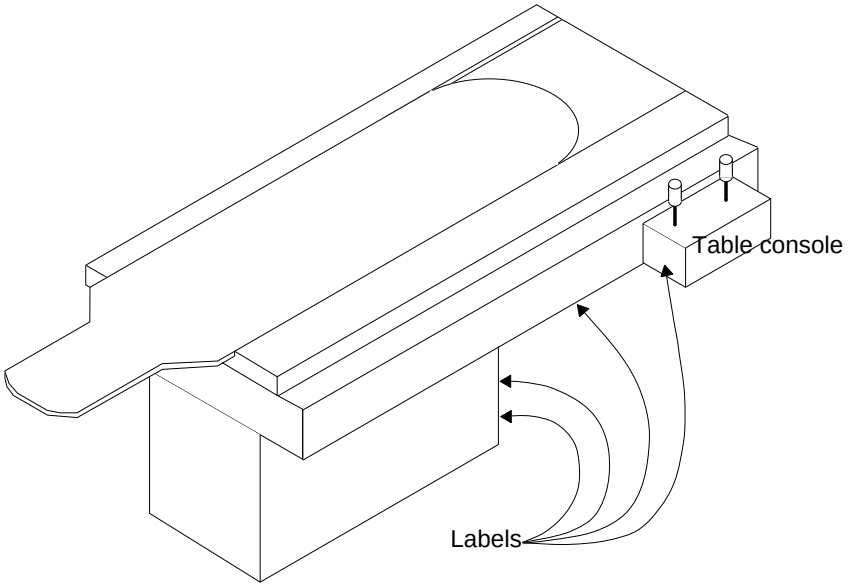


Figure 17: X-ray examination table provided with 4 labels.

What Device Type designation should be chosen in this particular case? One of those found on the table, or the one stated in the part list, which cannot be found on the table itself? The answer is clear, we must choose one of those found on the real object, because these are the ones that will be used in conjunction with maintenance and vigilance reporting, and, of course, it is not possible to report events with an object that cannot be traced. This means that we disagree with the manufacturer in the way they present their Device Types.

We have been using examples from the Siemens range of products to exemplify this problem, but the same issues can be applied to other manufacturers medical devices as well—though perhaps to a lesser extent.

Data hardware and software

There is an increasing tendency amongst manufacturers of medical devices, to take advantage of computer technology, often of the kind one would use at the office or at home—quite simply put, ordinary Personal Computers (PC's). This presents a problem when this type of equipment is to be registered in a hospital MEMS system. We have accepted the challenge from people who ask "*What do we do now?*", and constructed this set of guidelines that clearly define when a PC is to be considered (and registered) as a medical device and when it still remains, in its function, as a PC.

In Norway, the following draft is recommended as the main guideline for setting the boundaries for when computers should be registered as medical devices or in conjunction with medical devices.

What is medical electrical equipment?

The definition of what is classified as an Medical Electrical Equipment (MEE) is given through the following regulation:[3]

"§ 822.2.1:

Electrical equipment of any nature that is intended to be used medically for diagnostics, treatment, monitoring, etc. Accessories or additional equipment is also considered as a part of the medical electrical equipment. The same applies to connecting cables/leads and other functional connections of any kind or nature between devices".

If this regulation is to be adhered to, as it must, we can easily see that from this definition we will run into problems in defining, what is MEE and what is office equipment? A computer that is used, with or without a special program, to process the results from a medical device; lets say, a laboratory analyser, could just as well be used for word processing—and could thus be considered to be an office machine. How can we then differentiate between them?

Computers used in connection with MEE can be presented in 3 variations:

Case A

The patient is connected to an MEE that is taking measurements. The measurements are transferred via a cable or optical signals to a computer where the analysis of the information is carried out. The computer can also function as an operator's console managing the MEE (figure 18).

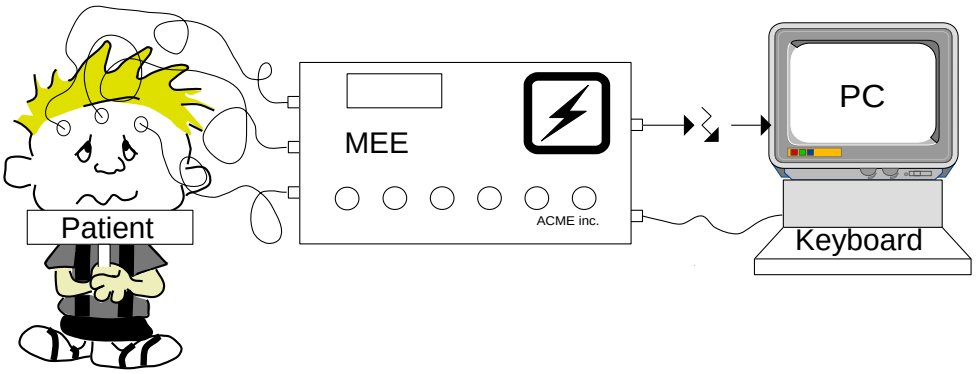


Figure 18: Case A.

Case B

The patient is connected to an MEE that is an integrated part of a computer, in the form of interface board(s) and/or software, that carries out the measurements and analyses the results (figure 19).

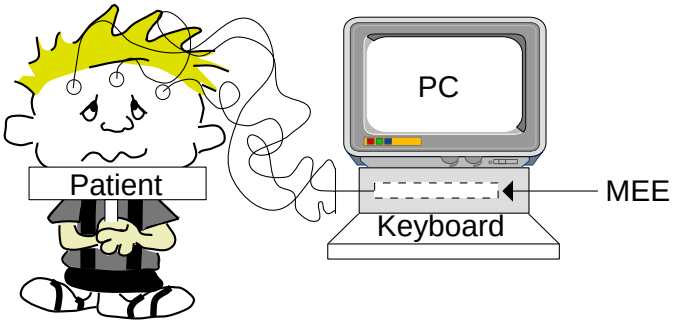


Figure 19: Case B.

Case C

The patient is connected to an MEE that is taking measurements. The analysis results are fed manually into the computer for further processing. The computer is in no way connected to the MEE (figure 20).

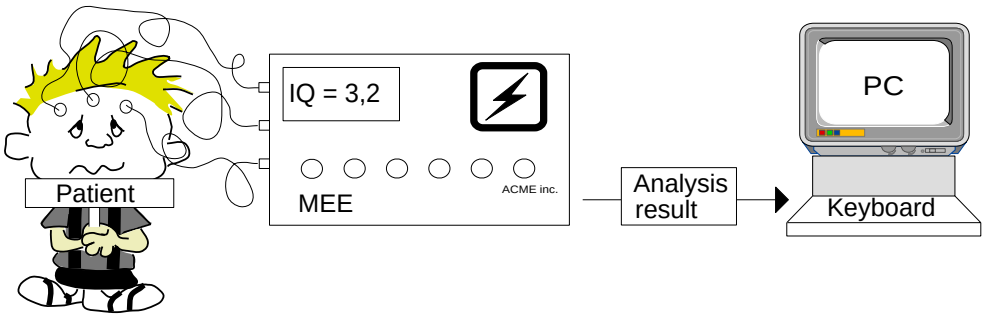


Figure 20: Case C.

Recommendation for registration

Bearing in mind the definition given defining MEE, the following recommendation forms the guidelines for how to register PC based equipment:

Case A

The device that is taking measurements should be registered with its own registration number and related to a Device Group term depending upon the nature of the device. The computer that is connected to this device should be registered with its own registration number using a term from the expanded list of the Device Group template **Computer, <specify>**.

Case B

The MEE must be registered by its function (e.g. **Spirometer**). (The term **Computer** must not be used when a MEE is an integrated part of a computer. This means that one cannot find this equipment in one's device register with a search for **Computer**(s), even though it differs from similar equipment only by its software/hardware.)

Case C

The MEE is registered according to the equipment's nature, as usual. The computer, in this case, remains a computer and is *not* considered to be an MEE, and is therefore *not* incorporated into the device register.

Problems concerning data exchange when lacking common rules for equipment registration

One may be led to believe that all the elements necessary for data exchange are satisfied when the Device Group register (nomenclature), Device Type register and local device registers are established, and the technical data exchange facilities are ready and workable. However, we still lack an important supposition that must be fulfilled before local events data exchange can be enabled—namely, common rules for equipment registration.

The NKKN definition of a Device Type is:

> A Device Type is identified by its *Make (manufacture or brand)* and *Model designation*, and is linked uniquely to one Device Group.

The main guideline here is that the Device Type designation is provided by the information supplied by the manufacturer on the device's label (type plate)—normally found on the rear, occasionally on the underside of a device. This is in many ways an easy and clear-cut method to use when establishing new Device Types. However, there are problems that inevitable arise, and these problems must be looked at and resolved:

How many units ought to be registered when the device is for example, a CT?

Without a set of permanent guidelines, it would be feasible to suppose that the following problems would arise:

At *Hospital A*, all the separate units of a CT scanner are registered as a whole; in other words, as one device only, see figure 21 (figurative depiction of a CT).

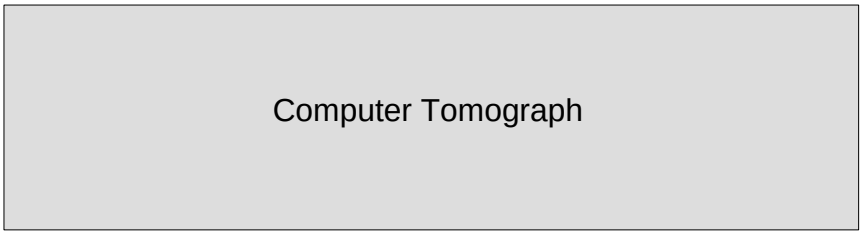


Figure 21: CT regarded as one device only.

This is because, this hospital does not have an adequate device nomenclature.

At *Hospital B*, all the units of the CT are registered as individual devices that are related to an installation in the MEMS' installation register, see figure 22:

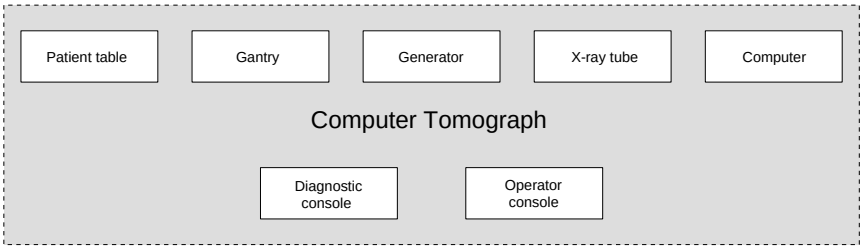


Figure 22: CT divided into 7 units.

At *Hospital C*, the same nomenclature used at *Hospital B* is available, but for some reason, one or more of the CT's units are left out during the acceptance and registration phase, precisely because this hospital did not have clear guidelines for the registration of devices (see figure 23). It is also likely that this composite unit was registered in a different manner, because the manufacturer has made this CT using different technical solutions. A CT could possibly be constructed with its computer as a separate device, or conversely, a CT from another manufacturer might have the computer and the operator's console built together as one device.

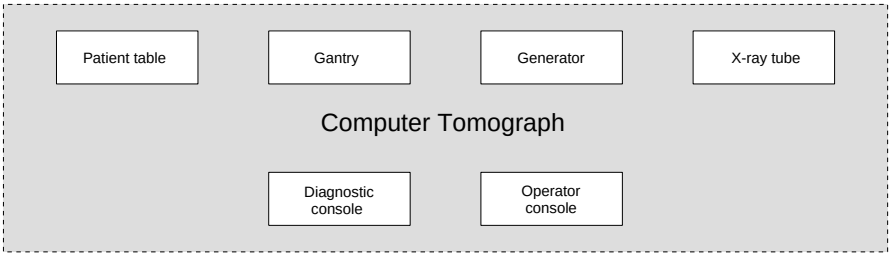


Figure 23: CT divided into 6 units.

When one, at a later date, tries to exchange data regarding; repairs, expenditure, device failures, etc.—this will not be possible, because in each case the devices has been registered in a different manner.

This example, we feel, shows clearly that it is not enough to agree about a national or universal data model for MEMS and vigilance reporting systems, but we also need guidelines of the same proportion, that stipulate how devices must be registered—as in the case of the CT, and how many separate units it is made up of.

All devices must be registered in one and the same manner, even though this will be performed by different people, in different hospitals or in other involved institutions.

What are the consequences (of merging towards a common MEMS/nomenclature system) where the aim is to produce a system that can truly exchange practical experiences by computer, or perhaps be able to send orders electronically for the purchase of medical equipment from your dealers?

• **A common nomenclature and Device Type register does not solve all the problems!**

It really makes little difference whether one has a good device nomenclature or not, if one is lacking a set of guidelines defining the procedure for what kind of equipment is to be registered, and how. No matter what kind of nomenclature one uses, there will always be ample room for the individual to make his/her own interpretations of which Device Group term a device should be given when registering equipment. A Device Type register that sorts all Device Types and connects them to a Device Group term, will automatically solve many of these problems for the user, taking the guesswork out of the job of selecting an appropriate Device Group term to a device, but:

• **Guidelines for registering equipment must be established!**

Even if we did have a standardised Device Type register where all Device Types are uniquely connected to a Device Group from the nomenclature, there will still remain problems unless we have a set of guidelines to follow. From the example given above, it does not necessarily follow that *Hospital C* registers its equipment in the same manner as *Hospital B*, even though they have access to the same nomenclature and Device Type register—this because no one has presented guidelines defining how this procedure is to be done. By Norwegian regulations, it is stipulated that every hospital must keep inventory of all of its MEE—including laboratory equipment. A definition of medical electrical equipment is also provided, but not how these devices should be registered. We have already addressed this problem regarding the heavy influx of computer equipment that are now being directly, or indirectly, used as medical devices, and we have presented our own draft to the Norwegian authorities.

Inevitably, we hope that all these questions which have been presented here, will be resolved through concerted actions in developing a totally new European scheme incorporating all the elements we have discussed. Only then can the intentions of the MDD be accomplished, and our energetic activities to steer the helm of happenings will be justified.

Equipment registration, the HUH experience

By *Equipment registration*, we mean the activity of registering all the relevant data/ information related to the individual devices into the hospitals inventory database, as outlined in Chapter 2 under the paragraph *General*.

The most essential feature of this action is the assurance of an unambiguous link between the registered data and the actual device as stipulated by national regulations: "*There must be an unambiguous agreement between the file and the different pieces of equipment*".[3] How this agreement is to be achieved is not mentioned, and it is left to the creativity of the hospital CED's to solve it. The process of registration is normally done in relation to the acceptance test when the device arrives at the hospital. The devices are inspected, and in many cases run through an electrical acceptance test.

Because of the complexities created through the shortcomings of most MEMS' systems, unstructured manufacturer's labelling, lack of adequate guidelines for the interpretation of the supplied device information there has hitherto been limited possibilities for ascertaining unique identification. The device's serial number together with its type designation will usually meet this demand, though in a large hospital hosting thousands of device records, it would not be uncommon to find that several serial numbers will coincide with those belonging to other devices of another make. Some devices—usually of older origin—might even be devoid of a serial number, or the labelling may be split up into two or three different labels lacking clues to which is bearing the serial number—as is often the case with laboratory microscopes. In other cases, the serial number may be stringed together with a lot or batch number—or even the model/type designation, and cannot be readily deciphered. And, of course, the serial number is almost always part of the label, often located on the rear or underneath the device, which, in the case of large devices may very difficult to find and read after it has been installed.

It has been common practice in Norway to strengthen this main aim of unique identification by allocating a local registration number and affixing this to the device in some manner. The advantage of this procedure is clearly the reproduction of a self created and controlled data field—a registration number that is unique both in the records and upon the object. We might end the discussion here and say: "*All is well, we've achieved unique identification!*". Unfortunately, this is far from the truth, and although a local registration number has many clear and practical uses in the everyday management of the hospitals equipment inventory, it also has clear limitations, many pitfalls, and at times can agitate confusion rather than clarity.

Taking the limitations first, it must be remembered that the registration number is a self appointed, internal hospital code that applies and functions within the bounds of the hospital, or at the most, in a county database. It serves no purpose to outsiders in the exchange of information, and can only act as a link between the inventory's theoretical world and the actual device. It may, incidentally, be quoted on a maintenance order or test

sheet when the device has been sent to the supplier for repair/service, and will then only function as a link back to the hospital's MEMS.

Secondly, the attachment of some form of labelling or numbering will also be limited by the nature of the device, as is the case with endoscopes, surgical drills, instruments, etc.—this due to cleansing procedures, hygienic reasons or extreme mechanical wear and tear. In these cases, the linking must be done via the serial number if this is provided. Though, it might be added, that technically speaking, there are now on the market electric etching machines that can neatly overcome this problem if so desired—ref. the paragraph *Types of labelling*.

Why registration labels?

There seems to be embodied within us humans a need to keep stock of what we have about us, or putting it another way—how large a supply of resources we have at our disposal. This is most certainly the case in our mental world, for we all possess some kind of collection of items that we like to keep stock of, whether it be postage stamps, miniature bottles of spirits, or even more bizarre artefacts such as ashtrays from hotel rooms. And so is the case, with perhaps a greater justification, within the hospital where the expanse of stock is so extensive that we are forced to make physical records and not just mental ones.

Sporadic attempts

At HUH, some of the earliest attempts at procuring an inventory list was done as early as 1970 by the Department of Anaesthesiology. Their reasons lay in the nature of their activities—which then—as is the case now, stretched all throughout the clinical part of the hospital, and their equipment likewise widespread. To keep an eye on things they registered all their equipment, as far as this was physically possible, with a consecutive number beginning with No. 1, logging this into a hand written inventory protocol and affixing the digits 001 onto the device. Self adhesive digits (marketed by the *3M* company), 3.5 cm tall and in brilliant orange (to denote the property of the Department of Anaesthesiology) were selected and affixed in an obtrusive manner (figure 24). This, of course, was to deter other departments from "borrowing" their equipment. No other information was recorded other than that of a self made nomenclature and the location.

NB! "Borrowing" in a hospital is often considered synonymous with "keeping thereinafter".

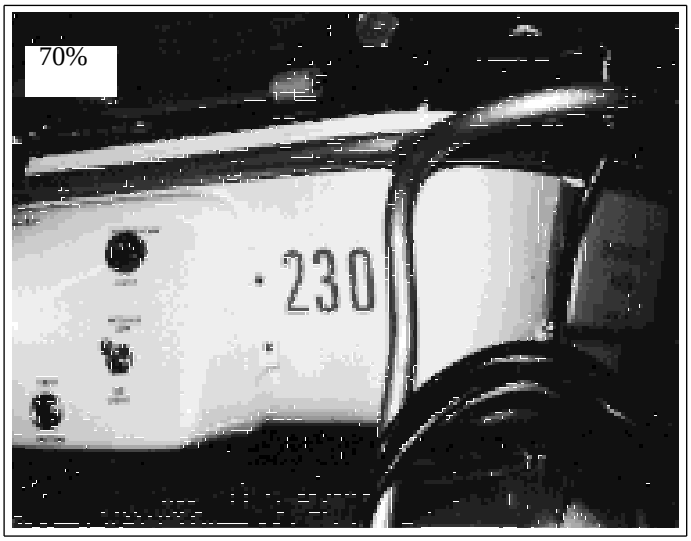


Figure 24:
The admonishing orange numbers of the Department of Anaesthesiology displayed on the front of an early Oxygenaire P661/66 ***Incubator Infant, transportable****.*

Another early effort was made by the Operation Theatre Department in 1975, then under the leadership of the Department Matron, Ms. Reidun Olsen. This department, which was a part of the large Department of Surgery, had for years been keeping their own accounts of the surgical instruments such as: scissors, tweezers, etc. belonging to them. Since their activities were divided between operating theatres on three floors of the old main building, plus some minor operating rooms and a urology treatment room, it seemed necessary to take stock of, and mark all of their equipment. It was generally understood that much of their existing equipment was around 30 years of age, and had seen better days. The basic idea was to collect information in an attempt to form a more controlled picture of the situation, such as how old was their equipment, how much repair work was entailed and when should it be replaced. This was initiated at a time when the CED was in the process of making its second attempt at registering the hospitals devices. Unfortunately the CED had made no effort to manifest their intentions, and in any case, it would have made little difference, for their inventory records were still logged on manual file cards. Oblivious of one another, the Operation Theatre Department proceeded to establish their own inventory list and did this by duplicating the number issued by the CED, where this had been furnished, or a self invented number in cases where the CED had overlooked the object. We must remember that, at this stage, there wasn't even provided a definition of what was, or was not, a medical device. A primitive label, where the number was stamped out upon a Dymo strip tape was produced, and affixed alongside the CED label, or stood alone (figure 25). Such labels had a bad tendency to adhere poorly, certainly to plastics, and often fell off as the adhesive dried up.

The registration number now designated was a two part numeric code, stringed together by a dash, with the first number being the departments code number and the second an incremental sequential number, e.g. *656-369* which was the registration number belonging to an early **Heart/Lung Machine, roller pump**.

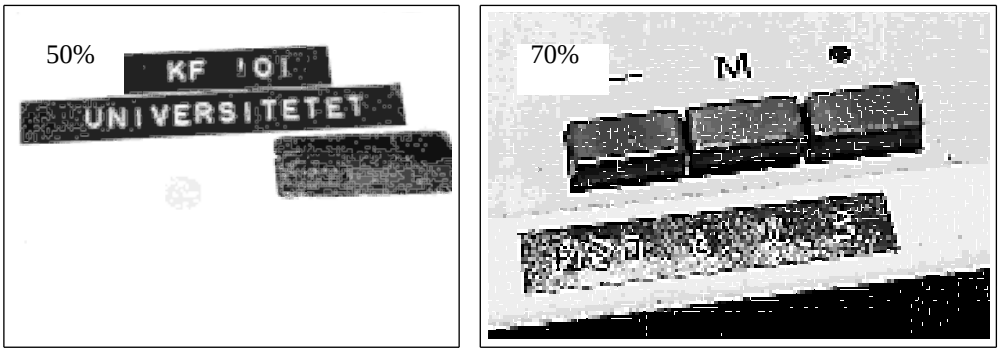


Figure 25: Some early examples of independent departmental labelling using the Dymo strip tape. Left: this picture shows an analyser belonging to the University of Bergen used in the hospital and is supplied with two types of labelling. Right: An ***ECG-apparatus*** *belonging to the Department of Medicine, examination clinic. Their Dymo strip label clearly illustrates the need for labels to show from a distance, and supply information such as who owns the equipment in clear text and not just in encoded form.*

Again the records were manually made and kept locally by Ms. Olsen. The system was cumbersome to keep updated, and lost its purpose when the CED transferred to the card index system.

[Source: Ms. Reidun Olsen, Managing Director of Central Operating Theatre Unit.]

First attempt by the CED

The CED began its first attempts at registering medical devices in 1974, using specially printed file cards that were to act as a manual information database (figure 26). The desired information was to be entered into the correct squares provided on the card. One card was to be filled out for each object. Looking back now, with the glorious wisdom of hindsight, just about every silly mistake possible was made. Again, the greatest failings were; the lack of a clear definition of what medical devices were, a total lack of any form for nomenclature and a gross underestimation of the magnitude and complexity of the undertaking made by the management of the CED. A supply of registration cards was handed out to the heads of all the clinical departments along with a letter asking for their assistance and a supply of blue coloured paper stickers, similar to postage stamps, that were to be stuck onto the devices, denoting that this device had been recorded. There was incidentally no connection at all between the sticker (figure 27), later known as the *blue label*, and the file card. Many departments did not respond, thinking this was a complete waste of their precious time. Practically all of the returned file cards were filled out bearing ambiguous information; self composed Device Group terms, scribbled unreadable writing and heavily adorned with corrections. It was, in short, a miserable failure.

APPARATUS FORM

Dept. for Anaesthesia

3445- 655 - 155

APP. DESIGNATION: Respirator	FACTORY MAKE: Blease		
DEPT.: Surgery Dept. 2.nd floor	TYPE: Bromten ventilator	SERIAL NO.:	
SUPPLIER: Plesner	PURCHASED (YEAR): 1973	APPROX. PRICE: NOK 5200	
ESTIMATED SIZE, MAXIMUM LENGTH: 45 CM, MAXIMUM WIDTH: 30 CM, MAXIMUM HEIGHT: 20 CM		APPROX. WEIGHT: 15 kg	
INSTALLATION SPECIFICATIONS (LIKE VOLTAGE, GAS WATER, TEMPERATURE ETC): $O_2 + N_2O$			
PURPOSE: DIAGNOSTIC / THERAPEUTIC: Therapeutic			
OPERATED BY: DOCTOR / NURSE: Both		USED LAST TIME: Dai/ly 19	
OPERATION EXPERIENCE: VERY RELIABLE / RELIABLE; SELDOM OUT OF O. / FREQ. OUT OF O.: Very reliable		OPERATING HOURS PER MONTH, APPROX.: 20 HOURS	
MAINTENANCE/SERVICE CARRIED OUT BY: Ola Nordmann		LAST TIME: / 19	
CALIBRATION - CARRIED OUT BY: Ola Nordmann		LAST TIME: / 19	
THE DEVICE CAN ALSO BY USED BY:		FREQUENCY:	
REQUIRED MODIFICATIONS:			
THE DEVICE CAN/SHOULD BE REPLACED BY:			
COMMENTS:			

CLINICAL ENGINEERING DEPT.
HAUKELAND UNIVERSITY HOSPITAL

Figure 26: The first file card (translated from Norwegian) showing some of the rather futile information requested to be rendered. Take notice of the device's (apparatus') registration number in the top right hand corner, which is made up of three parts. The first number, 3445, is a code from the old Norwegian NIS-code which was, in a sense, divided according to both anatomical and treatment related issues. Block 34 included all "equipment for sustenance of body functions" and hence, 34 45 00, was a respirator. The middle number, 655, is the department code for the Department of Anaesthesiology, and the last number, 155, is the individual equipment registration number.

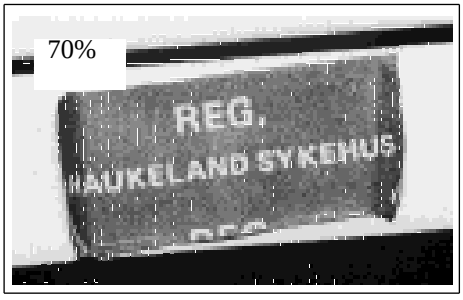
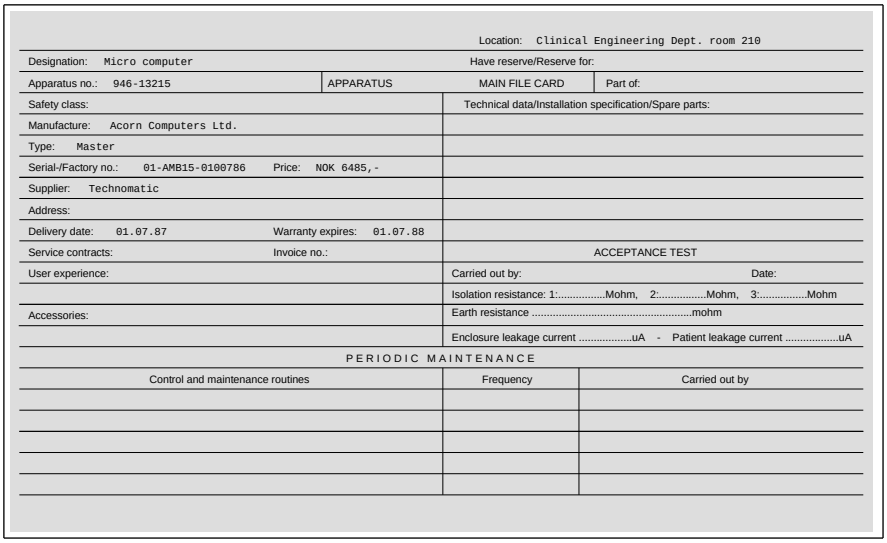


Figure 27:
The very first CED label used at HUH indicating that the device had been registered. The label is affixed to the front bottom edge of a WISAP model 5 ***Insufflator, carbon dioxide****. A close up of the label shows the abbreviation REG., for registration, and Haukeland Sykehus (Hospital). The only link provided is through the manufacturers designations.*

The second attempt by the CED

The second attempt was initiated in 1975/76 by the newly employed manager of the CED, Mr. Arne Godal, who also understood the need for a systematisation of the hospital's device inventory. It was easily apparent that the work would have to be started from scratch. The file cards were modified—size, weight and use, were amongst other things, dropped because we considered this information to be of very low grade value—and it was, as time had proved, very rarely of interest. The new file cards (figure 28) actually carry a layout that was to form the basis for the device registration screen layout in our MEMS of today. A new, self adhering, washable and detergent proof label was found to be adequate for the job (figure 29). Two of the CED's employees were allocated the mammoth task of trawling the hospital room by room. An assistant appointed by each department helped to explain what each piece of equipment was, and was used for.



		Location: Clinical Engineering Dept. room 210	
Designation: Micro computer		Have reserve/Reserve for:	
Apparatus no.: 946-13215	APPARATUS	MAIN FILE CARD	Part of:
Safety class:		Technical data/Installation specification/Spare parts:	
Manufacture: Acorn Computers Ltd.			
Type: Master			
Serial-/Factory no.: 01-AMB15-0100786	Price: NOK 6485,-		
Supplier: Technomatic			
Address:			
Delivery date: 01.07.87	Warranty expires: 01.07.88		
Service contracts:	Invoice no.:	ACCEPTANCE TEST	
User experience:		Carried out by:	Date:
		Isolation resistance: 1:.....Mohm, 2:.....Mohm, 3:.....Mohm	
Accessories:		Earth resistance .....mohm	
		Enclosure leakage current .....uA - Patient leakage current .....uA	

PERIODIC MAINTENANCE

Control and maintenance routines	Frequency	Carried out by

Figure 28: The second version of the file card (translated from Norwegian).

In the mean time the *Norwegian Electro technical Committee (NEC)*, in which Mr. Godal was a board member, had recommended the establishment of a new body for electrical surveillance in the health sector. This activity was commissioned by NVE to a privately owned company: *TELOX AS*. Despite much friction between TELOX and hospital owners, incited through the preposterous mandatory inspection fees that had to be annually paid, TELOX imposed upon the hospitals, through NVE regulations, a mandatory system. They also suggested a registration number code link to the object, hence the system of the national department codes (enforced by the Ministry of Social Services), followed by an unambiguous number for each device, e.g. *203-757*, (which in the example shown, is the department code for the Chest Department followed by the sequential number separated by a dash). They also referred to the *NIS nomenclature*, a Norwegian translation of the Danish *DIS code*.

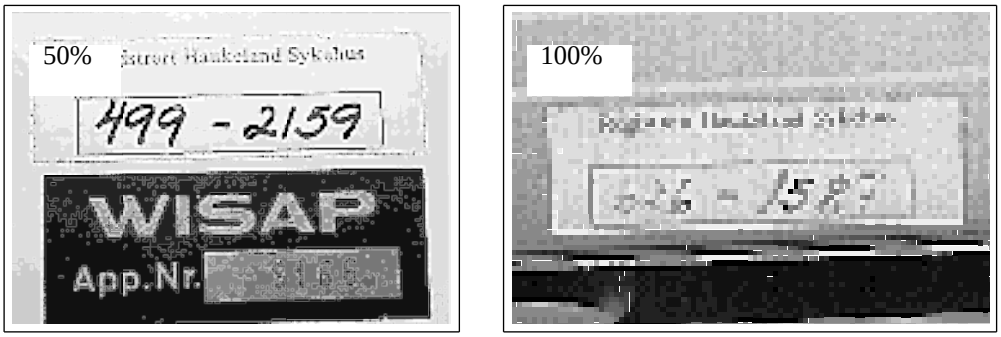


Figure 29: Shown on the left is the washable "White label" provided with the text, in translation, "Registered Haukeland Hospital", and coded with the department code followed by a dash and the sequential number. This was incidentally found on the rear of the WISAP model 5 ***Insufflator, carbon dioxide*** *shown in figure 27 having been registered a second time in the second attempt. To the right we can see the remaining exposed text of the marker pen that has fared less well than the label.*

Although the CED had to retrace some of its tracks on the second attempt, they got underway with the task that was to form the basis of today's device inventory. Mr. Godal recalls that there was quite a stiff resistance to be found, especially in the departments of Neurology and Medicine, to this interference created by this newly established department of engineers that had no knowledge of medicine.

The new label, which we call the *White label*, survived the detergents, etc., though the glue did tend to get tacky through time—but the ink of the marker pens used to write the code number onto the labels, fared less well (figure 29). [Source: Mr. Arne Godal, PROTECH AS]

The card index system

In 1980, HUH was in the hectic process of evaluating masses of new equipment and technology ready for the purchasing process. All of this was to be tested and installed in the new central block, forming Norway's largest hospital and building (measured in sq. meters). It was apparent that the inventory system, still using file cards sorted in file boxes, could no longer be maintained, and besides—measures to meet the regulatory obligation of running a maintenance log, had to be taken into account. A new card index system was proposed and adopted (figure 30, 31). All the information from the file cards was typed over to the card index cards along with the corresponding registration numbers. Little did we realise then, how much confusion we were actually creating for the future to come—this as futile information registered by unindued workers—transferred from one system to the next, and it would be indeed, finally carried into our first computerised database like a kind of virus.

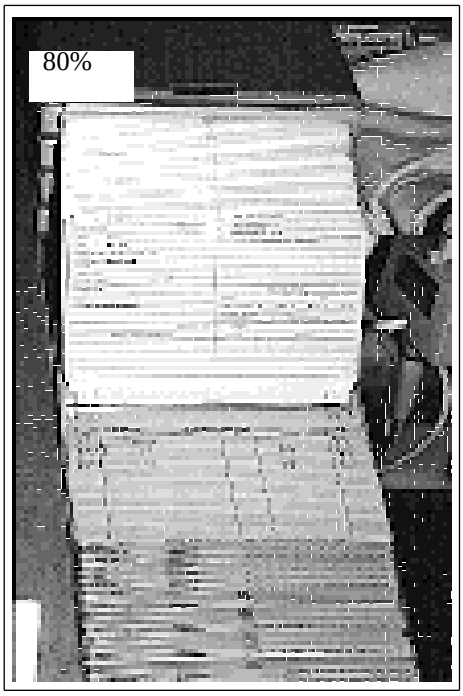


Figure 30, left: The only existing card index system to be found at HUH and still in use in a small workshop for repair work on laboratory microscopes. Right: All the cards have been manually typed and often duplicated from the central register. A formidable job!

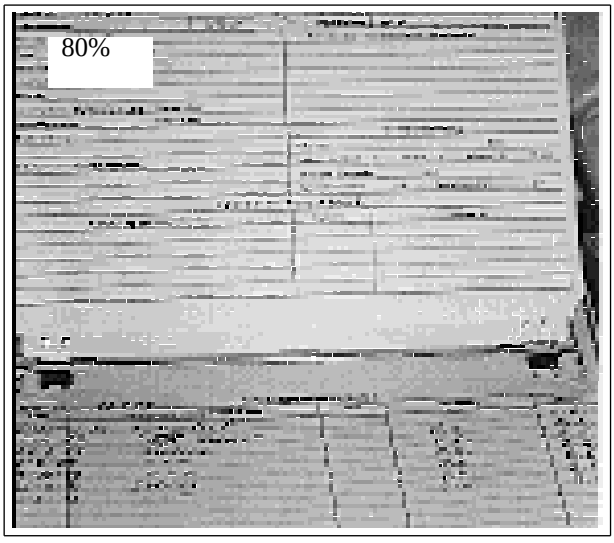


Figure 31:
The upper card shows all the device information, whilst the lower card is for entries made by the engineer of all repairs and service work. As one can see, this type of manual system does not evoke much input of information from the engineer.

But in the long run, this would prove to be the catalyst needed to invoke the restructuring of our work—see preface—and in turn, turn the tide to the well contemplated work of today.

Some examples of such absurdities are well worth looking at to see how easily confusion is created:

A `Bennet PR-2` respirator, was registered with the manufacturer as being *Santa Monica*.

All the information on these particular respirators is painted by way of stencils directly onto the casing of the respirator head, and manufacturer/model/factory address/patent no./user instructions can be extremely difficult to distinguish. Santa Monica was of course part of the manufacturers address in California (figure 32, 33).

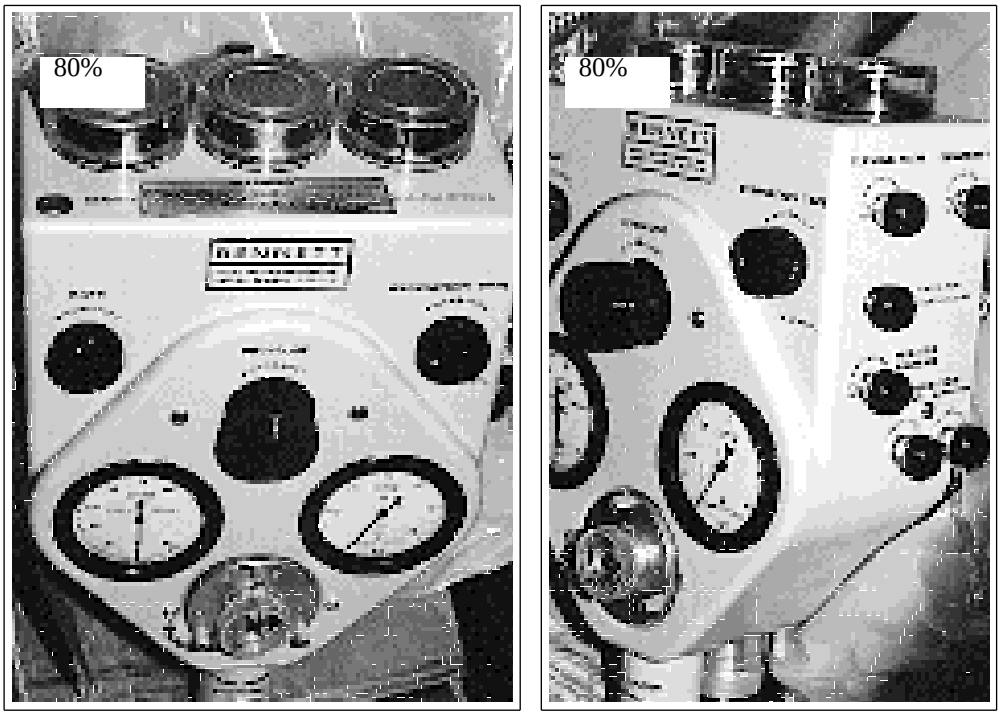


Figure 32, left: A view of a BENNET PR-2 respirator head, showing, what can be for inexperienced personnel, a confusion of information. Right: A side view showing user instructions.

Strange Device Group terms such as *Coulter Counter*, read directly from the company name, found on this type of analyser became a part of the nomenclature. And even more flamboyant Device Group terms such as *Friedman Visul Firell* also crept into the nomenclature without anyone having the slightest idea of what this could be. It was by coincidence, eleven years later, discovered to be an analyser for Glaucoma (**Ophthalmo, analyser glaucoma**) and the Device Group term was duly corrected.

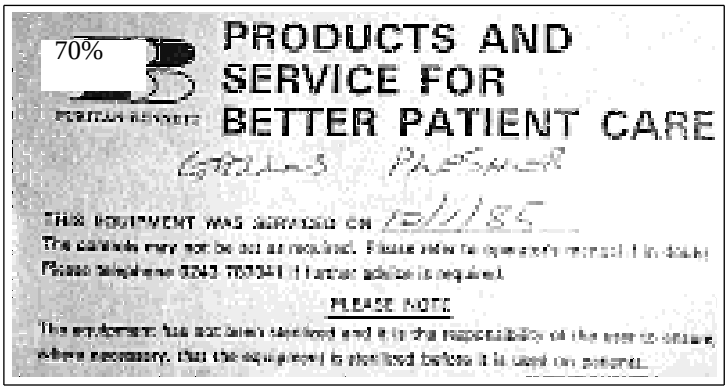
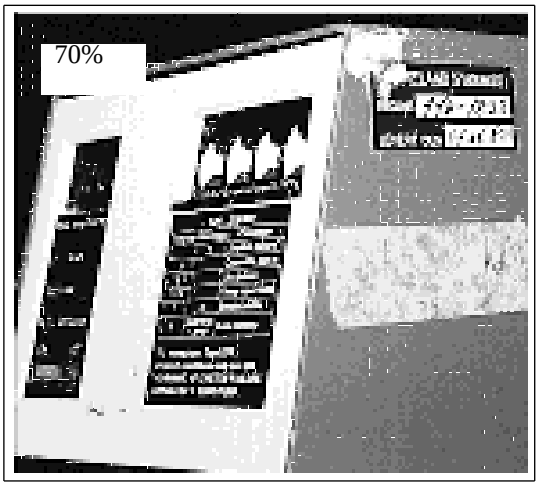


Figure 33:
A service tag found alongside this obsolete ***Respirator, ordinary*** *showing a change in the company name—from Bennet to Puritan-Bennet.*

Since there was to be a massive influx of new equipment, two other important measures were taken. The first and obviously, most needed, was a new registration label. This time the market was scoured for a label that would adhere permanently—and where the number code would remain protected, no matter how fierce the cleansing procedure should be. It was anticipated that equipment exposed to autoclaves would not have such a label affixed to it, and would be registered through their serial number only. The new label is known as the *Red label* version 1 (figure34), and it employed two fields of information; the number code as earlier described and the date of acceptance by the CED. This label was provided with a transparent plastic film that was sealed over the text after the backing is removed, in the manner of a protective window (figure 34, bottom right—which incidentally shows the *Red label* version 2). It is supplied by the company *Barra AS, OSLO*.



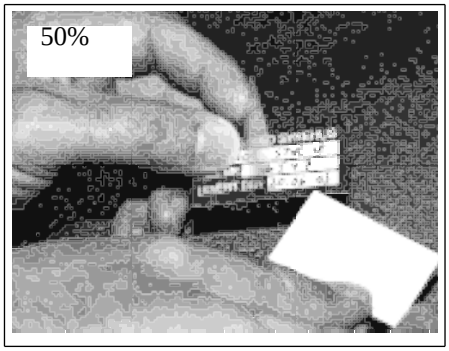


Figure 34, above: The new Red label—version 1, shown affixed to the side of a Valleylab I.V. 5000 ***Infusion, pump ordinary****. Top right: The close-up picture of above shows the text as being: Haukeland Hospital, Registration Number and Delivered the (date of acceptance). Bottom right: The label's protective transparent film is being sealed over the text.*

Again, marker pens were used to print on the correct information and it can be reported that, in the twelve years of use, neither the label adhesive nor the window have succumbed to the adverse environment to which they are subjected. At last the label coding was secured, or so we thought.

The second measure was the move to a new range of consecutive numbers starting at No. 10000. This would instantly differentiate between the old equipment, bearing the *White label*, and all of the new to be installed in the Central Block opened in 1983.

Two setbacks that were not anticipated brought about new lessons and changes. The first was the quality of our marker pens, which though marketed as permanent ink or indelible to detergents, were not at all fade proof and surprisingly faded to a blotchy yellow in an alarmingly short time (figure 35). A new type of marker pen was found and this time tested in a special light unit, designed for the purpose of exposing fading durability in materials. This pen is produced by *W.H. Brady Industrial Products Division, Milwaukee*.

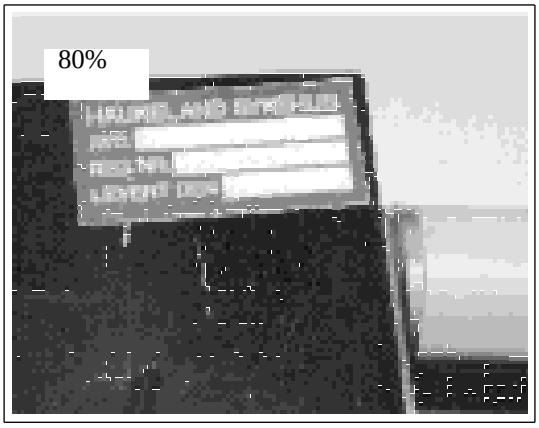


Figure 35:
The effects of sunlight/intense artificial lighting on the early types of "indelible" marker pens. The hand printed information in the white squares has faded to an illegible yellow blotch.

The second blow came when a new national hospital department code, expanded to 4 digits, was imposed—again by the Ministry of Social Security, rendering all our registration labels obsolete. For example, the Central Operation Theatre Unit's code was changed from *656* to the new four digit *1900*. This change did not really affect our registration number system (*656-369* mentioned above should have been changed to *1900-369*), since we simply chose to ignore the department code prefix.

Again, the remedy was to learn and adapt. A new *Red label—version 2*, much the same as the previous one, with an additional field for the department name was made (figure 36). In fact, most departments appreciate their name rather than their code being displayed upon their devices, whereby they are able to retrieve borrowed equipment more easily—the deterrent factor. The registration number is now only an incremented sequential number, automatically generated by the MEMS, but we do have a built-in override system—just in case!

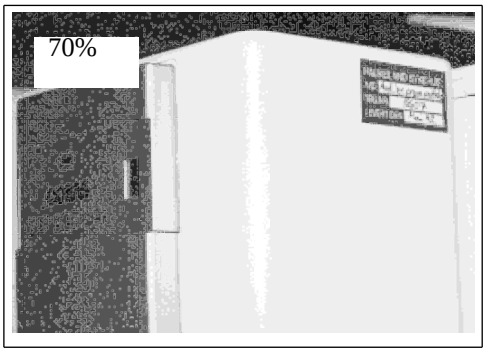


Figure 36, left: The Red label—version 2, affixed to a Cobas Laboratory ***Lab-Equipment, tip server****. The close-up picture shows the new third field, (AVD.) for Dept. or Department, where the owner departments name can be filled in. The registration number is now purely a sequential incremented number that carries no information in itself.*

Right: This clearly shows that departments like to have their name spelled out on their property. Here the department has added their name by means of a DYMO strip tape directly above the CED registration label, Red label—version 1, that was devoid of the Department field. The equipment is a Siemens-Elema Mingocard 34, ***ECG- Apparatus****.*

Since these early days, the CED at HUH has transpired through two phases of computerised MEMS. The first, a MAIntenance SYstem (*MAISY*), constructed for offshore oil rigs was introduced in 1985 by the fourth Department Manager, Mr. Trond Fagerli. This was a bold venture that; through the adoption phase, the running in period and its short existence, was to give us the experience required to see the shortcomings of this and most other systems—both in MEMS and coding and classification. In 1988, a HUH team began the undaunted task of developing version one of the MEMS named MÉRIDA, using the CED at HUH as a test laboratory. This, and the conception of a user-friendly system with a core of protected data, is most probably the reasons for the success and recognition of this work. This was to lead us all through a massive phase of development; both departmental, nationally, through the AIM/BEAM research project and in contact with CEN.

Types of labels

Should one decide to go ahead with a registration number coding and labelling system it will be well worth to spend some time to investigate what your intentions are to be, what kind of functions you wish to cover, what kind of devices will be involved—and of course what kind of labelling will be required. As we have already seen, starting without giving thought can be extremely costly and tedious—and most likely create inconceivable confusion. Labelling or direct marking can be done in a number of fashions or probably in a combination of manners to achieve the goal.

Ways of labelling could be:

1) Paper labels.

2) Plastic labels with marker pen.

3) Plastic labels with protective window.

4) Aluminium foil labels with typed code.

5) Electronic lettering system with bar code.

6) Etching machine, direct upon the device.

7) Inscribing tool/machine, direct upon the device.

8) Engraving machine, plates/tags/discs.

To illustrate the diversity of these different labelling types and methods it is interesting to see what can be implemented; all for the sake of systematisation, control and inevitably—Quality Assurance for the patients safety.

1) Paper labels.

Paper labels do have little value for long term use, say for more than up to two years (figure 37). They can therefore only be used to carry short term information, such as an *Inspection or maintenance completed* label (figure 38).

2) Plastic labels with marker pen.

Plastic based labels are very durable and can be easily adapted to curved surfaces or even quite uneven surfaces without fear of detachment. The problem will be the unprotected text.

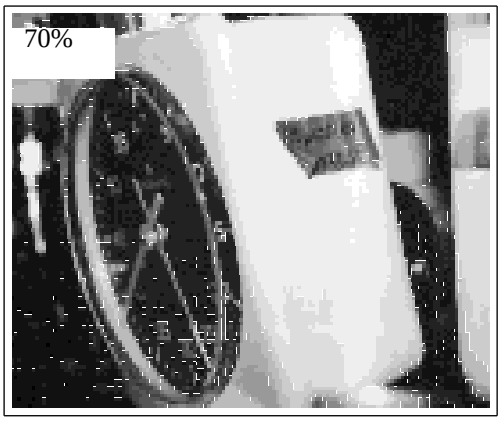
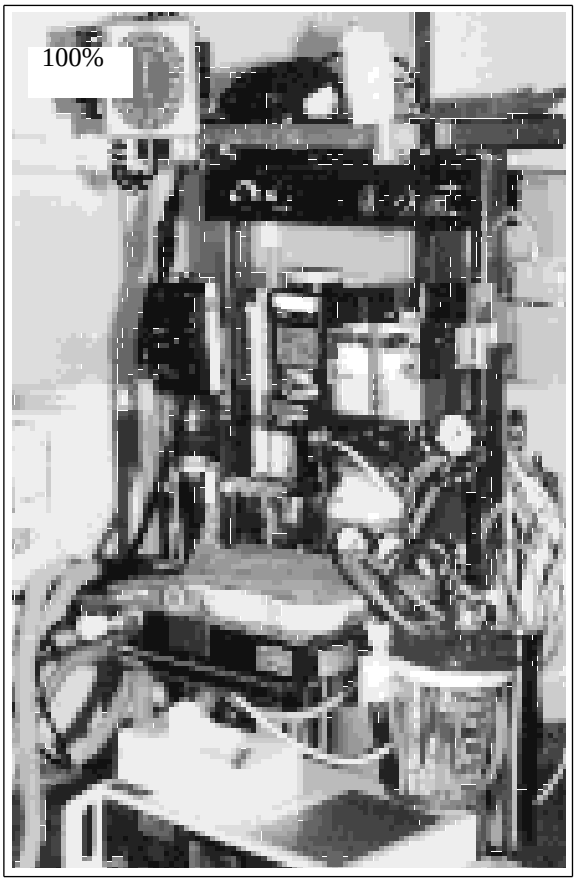


Figure 37:
This is a paper label issued by the Department for Anaesthesiology which was affixed to all their small equipment in an attempt to differentiate between its many sections. This label, attached to a Junghans stop watch, denotes that it belongs to the outposts. This type of label is vulnerable to the vigorous cleansing procedures found in hospitals and becomes mostly unreadable.



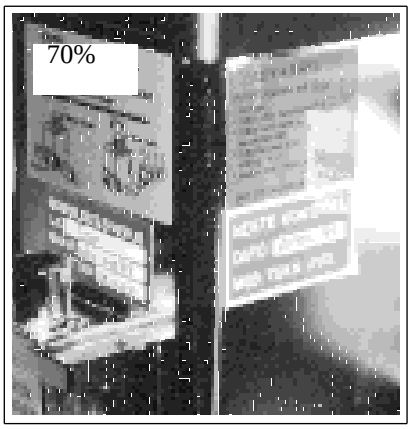


Figure 38, left: On the forward edge of this ***Anaesthesia, Anaesthesia Apparatus*** *and on the side of the Vapouriser can be seen the green "Inspection or maintenance completed" label used at HUH.*

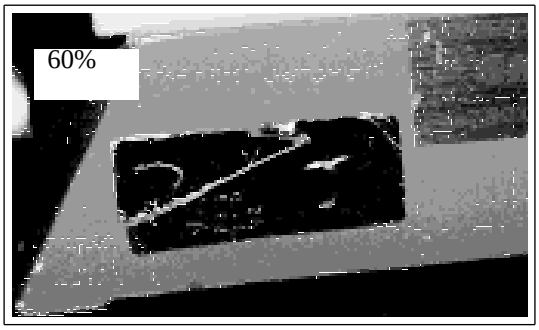
Right: The green label, affixed to the side of the Ohmeda Isotec 4 Vapouriser, is of the plastic based, window protected type—and the text is; NEXT CONTROL, DATE ..., CED. This label is used in conjunction with preventive maintenance, and is renewed after this has been carried out. The date for the next planned action is written on the label, and it has a definite positive effect upon the users who are quick to inform the CED if the date has expired, and no action has been taken. For this kind of job, a less expensive paper type label would be equally suitable.

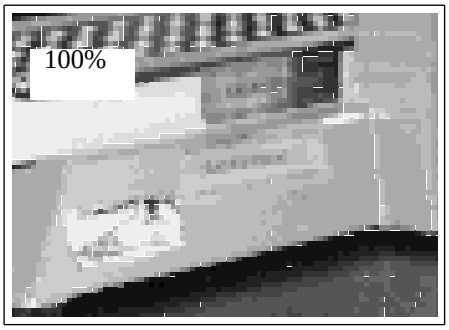
3) Plastic labels with protective window.

Plastic labels with protective windows is a sure method, provided the marker pen or whatever is used, is guaranteed fade proof.

4) Aluminium foil labels with typed code.

Aluminium foil labels are very popular and seem at first to fulfil the task neatly. Unfortunately this is not the case, as they are very susceptible to mechanical wear and tear (figure 39).





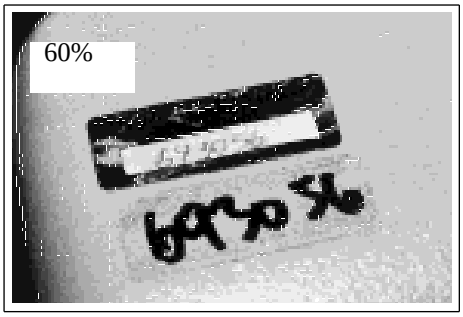


Figure 39, above: An aluminium foil label affixed to a piece of laboratory equipment belonging to the University of Bergen at HUH.
Top right: A close-up picture shows how mechanical wear and tear has rendered this label useless.
Right: Another version of this type of label with the number code field applied as a special coating for the admittance of the code by ball point pen. This is the same coating found upon most credit cards. The number is altogether unprotected.

5) Electronic lettering system with bar code.

The Electronic lettering system, *P-TOUCH8000* offered by *Brother office machines*, should be worthwhile investigating. It produces labels in 6, 9, 12, 18 and 24 mm widths using a self adhesive plastic tape with a protective window. The text can be self composed and may be bar coded. At the time of writing this book we are not able to elaborate about the quality of this product, but it certainly looks very promising.

6) Etching machine, direct upon the device.

An etching machine (figure 40) would normally not be an attractive method for labelling ordinary devices. However, this method could provide us with a marking system that would certainly apply to equipment/instruments that are to be subjected to harsh disinfection treatment or autoclaves—as discussed in the paragraph *Equipment Registration*. At HUH, etching the hospitals full name boldly onto objects such as typewriters, printers and other office machines has been practised for years (figure 41). It could well be that such drastic measures might be needed for certain types of equipment that are rapidly becoming

commonly used as medical devices, such as; video recorders, personal computers, etc. A video recorder, *Panasonic super-VHS*, costing NOK 18,000, was purchased as part of an ultrasound imaging unit, and although labelled in the customary manner it was discovered missing and presumed stolen from the examination room, after only two weeks.

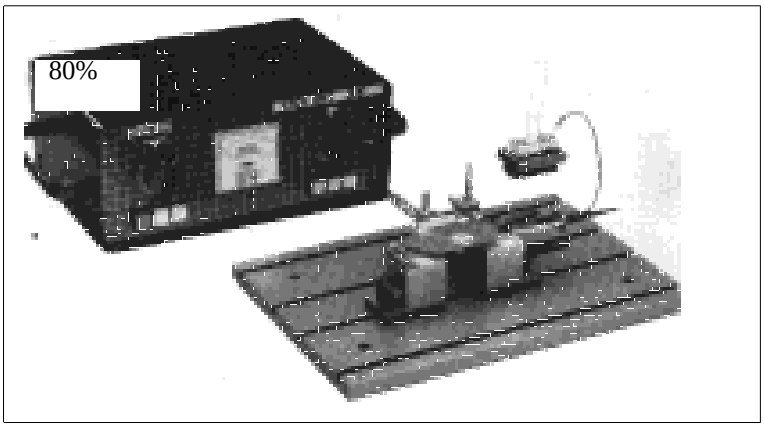


Figure 40:
A small etching machine that could be used in the CED for the marking of devices that are unsuitable for marking with adhesive registration labels.

Figure 41:
A Qume LCS-130-4 ***Printer*** *with the hospital name clearly etched into the main casing, thus deterring theft.*

7) Inscribing tool/machine, direct upon the device.

The use of an inscribing tool/machine for marking devices seems too harsh a process, and it would be reasonable to advise not to use such a method.

8) Engraving machine, plates/tags/discs.

Engraving can be a useful method of marking/labelling— though not directly. By making tags or discs that can be attached to the device or it accessories, one can achieve linking and traceability. It is interesting to see how such a robust form of labelling can be utilised as an aid to achieve the necessary linkage between the actual actions taken, and the records of these actions.

Figure 42 shows the underside of a *Stierlen Maquet* type `1.494`, **Heating Pad, electrical**. It is registered in the usual manner with the registration label affixed next to the manufacturer's label. A round green disc with the number *6* engraved into it is attached to the connecting power cables of the pad. These heating pads will lie on top of the operating table, ready draped, and it is therefore impossible to see either the registration label or the manufacturer's label when the patient is lying on top of it. Because the risk of pressure sores being mistaken for burns—and since such traumas usually become evident afterwards, when the patient is lying in the recovery unit—all use of heating pads is recorded in the patient's anaesthesia journal by way of the green disc, in this case *No. 6*. In the event of any incidents the heating pad involved can be located, and its registration number will provide the link to the MEMS for job history etc.

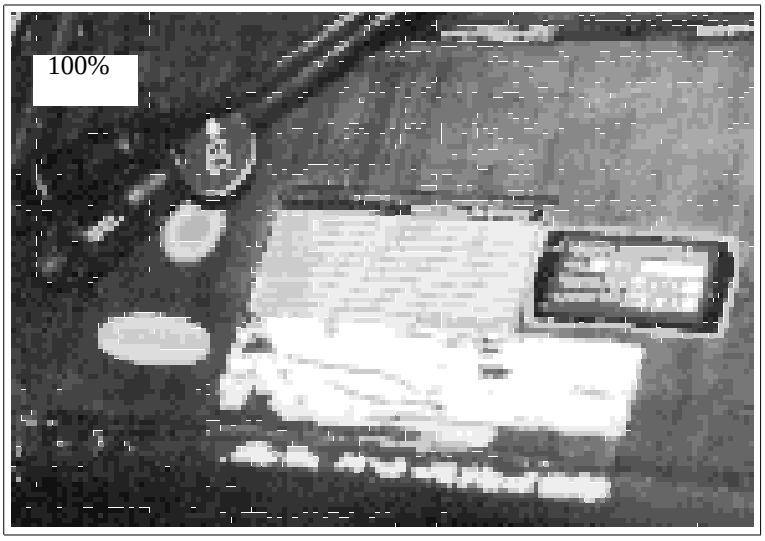


Figure 42: The green numbered disc forming the link between the practical use of the ***Heating Pad, electric*** *and recorded information.*

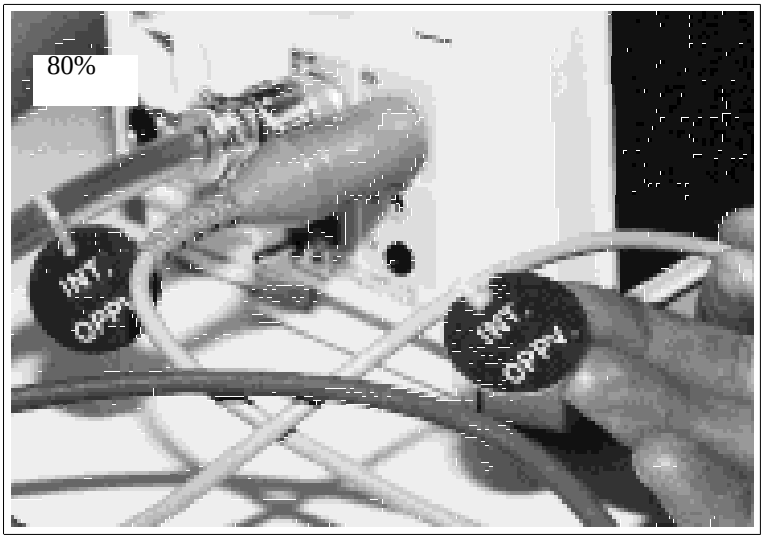


Figure 43: Engraved discs (labels), here used to identify the owner department of these expensive probes and ECG cables belonging to a Propaq ***Monitoring, bedside unit****.*

Other label functions

Other functions for labelling can be an intrinsic part of the registration label. Some quite interesting features concerning this matter have been in use at HUH for several years, and are certainly worth mentioning:

In large hospitals, the idea of setting up an equipment pool will usually have been discussed to some extent. There are the pros and cons to be considered, and any final decision will not be easy to arrive at. At HUH, we have more than once been caught up in such discussions, but so far we have not established such an equipment pool. We do though, have certain devices that are administered through and by the CED for short term loan only—this to alleviate acute shortages whenever they should arise in the clinical departments. These are; ten infusion pumps, fourteen enteral feeding pumps and a couple of backup devices such as bedside monitoring units and defibrillators.

In order to ascertain their return, after use, to the CED from the borrowing department, these devices are labelled with an additional *on loan* label (figure 44). It is, of course, not always easy to get the loaning clinical departments to "play fair" and return such equipment after use—but we do, however, have the loan registered in the MEMS thereby securing traceability.

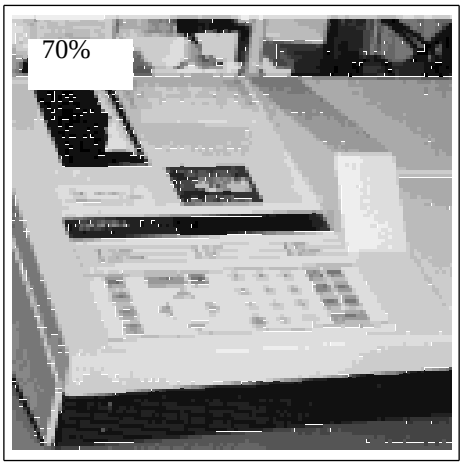
Another interesting feature that was developed, came from the ever annoying and un-controlled influx of *borrowed in* equipment that at times haunts all hospitals and health institutions. It is not an unknown fact that this has been used as a policy by physicians, departments and suppliers alike to force acquisition of equipment, though this might not be at all in keeping with the hospital purchasing policy.

Figure 44, left: An IVAC 591 ***Infusion, pump ordinary*** *belonging to the CED's equipment pool for loan set up to meet acute needs within clinical departments.*
Right: The red label at the top of the picture is the CED's "on loan" label, announcing that this equipment is purely for loan and that it belongs to the CED at HUH—and that it MUST be returned after use. It can be seen that the bottom red label is a normal registration label basically saying the same thing. In our next issue of the "on loan" label, these two labels would be combined into one.

At HUH, we differentiate between the two ways equipment can be borrowed in:

a) If a device is borrowed for the purpose of trial, testing and evaluation, or as a temporary replacement for equipment that has been sent for repair—it is then considered to be borrowed for a limited time span only. This device is registered as normal, but with the owner being the supplier and the *borrowed in* label attached to it (figure 45). The device is registered in the MEMS as usual, perhaps with a time aspect noted. When the device is finally returned, either the borrowing department or the supplier will inform the CED so that its status in the MEMS is changed from *Borrowed in* to *Returned*.

b) If, on the other hand, the device is borrowed on a long term basis, this usually indicating that the hospital can keep it as long as that supplier delivers the disposable products/medicines linked to its usage, then the device is considered by HUH as being on permanent loan. In this case the device is registered as belonging to the hospital. There is at the time of writing, considerable numbers of devices borrowed by HUH on this basis, and we have so far not recorded that any supplier has ever reclaimed their equipment against the will of the hospital.



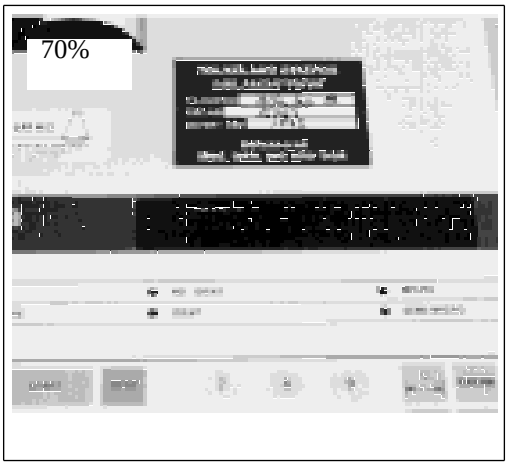


Figure 45, left: A Sebia DVS 100 ***Analyser, photometer ordinary****, borrowed from the Norwegian supplier ALFA LAB AS by the Department of Clinical Biochemistry for evaluation.*
Right: Here we clearly see the "borrowed in" label with three fields of information—the suppliers name, the registration number and the date of delivery. The bottom text is: "To be returned to the Clinical Engineering Department after use". This device was returned in November 1993.

Registration number constructions

When taking into use a numeric code, it can be easily read and communicated between all user levels and computer based information systems. The draft *ISO/IEC JTC 1/SC 14*[18] can give some advice and indication of how such codes should be constructed. The CED at HUH chose to base its' registration code upon a non-significant, sequential incremental numeric code only.

In April 1982 a new code based upon nine digits was introduced (00000.000), starting with the first number at 10000. The last device coded using the old code (starting at No. 1), was a `Valleylab Infutrol`, **Infusion, pump ordinary** allocated the code *2779*. This infusion pump was incidentally taken out of use and destroyed in August 1990. Since the introduction of the new code in 1982 we have now reached registration number *17650* (in April 1994), thus giving the reader some idea of the capacity that is available.

Sometimes a necessity for inbetween codes may occur. This can be provoked by a desire to cluster devices that naturally belong together such as a complete X-ray unit registered as many devices, or complicated laboratory equipment (figure 46). To obtain such a possibility, our very first computer based registration system employed a real number, with 3 decimal places, as the registration number. The normal procedure was then to increment the registration number by one, when picking the code for the next device to be registered. This procedure left us with 999 inbetween codes for the purpose of clustering devices.

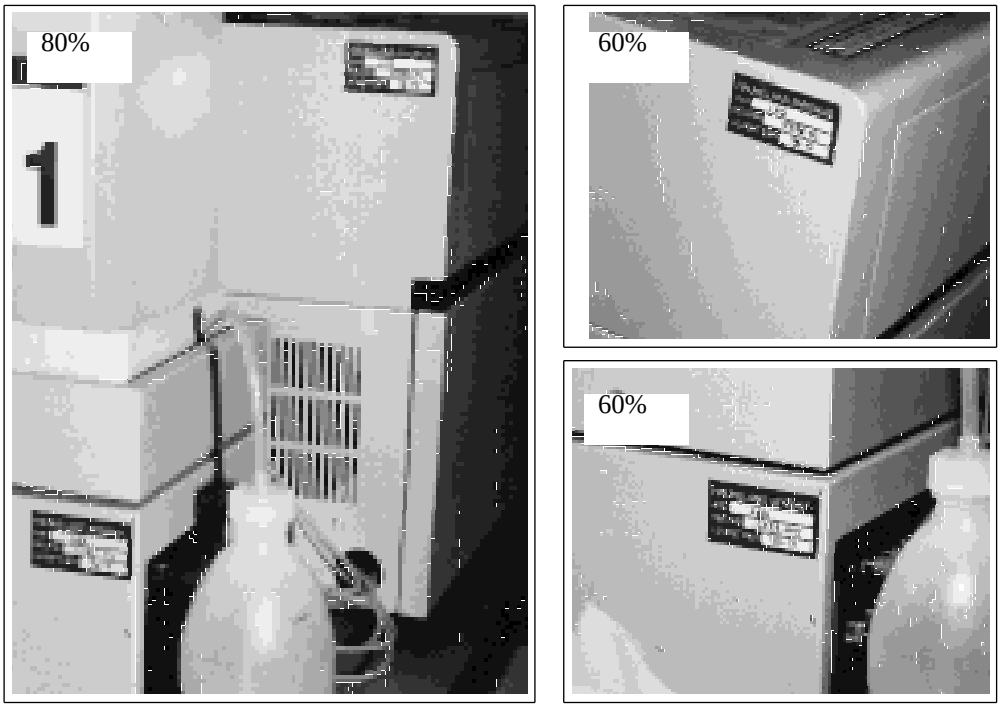
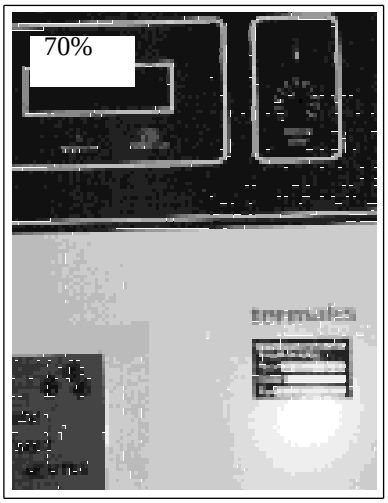


Figure 46, left: A piece of laboratory equipment comprising two units.
*Top right: The main unit, an **Analyser, chromatograph HPLC compact**, has been allocated the register number 15288.000.*
*Bottom right: The sub unit, a **Lab-equipment, deaerator**, is registered 15288.001, thus strongly suggesting that these two units belong and work together as one.*

This is, however, an old fashioned way to cluster devices—it is now being achieved by utilising an *installation* register in the MEMS. Also, this way of assigning codes is in fact a violation of the rules for a non-significant code, and is now abandoned for registration. But, in order to obtain backwards compatibility with our old MEMS, we have retained the possibility of using such codes for the time being. Our Technical Department is also a user of the management system, and since they still insist upon using significant coding, we have to keep this feature in their version (figure 47).



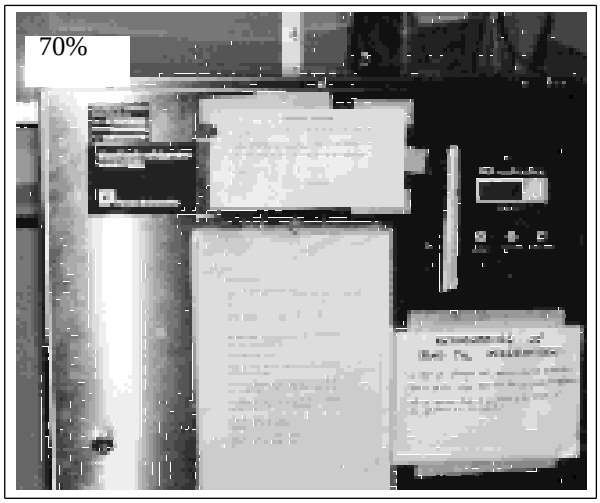


Figure 47, top left: A registration label used at HUH by the Technical Department is affixed to a Termaks ***Lab-Equipment, cooling cabinet****, which in this case is, in a manner of speaking, a permanent fixture having been built into the wall.*
Bottom left: The registration number is a significant code, having intelligence structured into it. The number is: 304401.204. The two first digits denote the building (30 = the central block). The next two denote the equipment classification (44 = Loose mechanical equipment). The next two are the device group (01 = Refrigerator). The last three is the sequential number (204).
Right: This is a Forma Scientific ***Lab-Equipment, cooling cabinet****, again registered under the same system of intelligent coding. This piece of equipment is loose and if it is moved to another building, thus rendering the code incorrect—then it has to be changed accordingly. This situation will be a daily event for many hospital devices suggesting why such a coding system should be discouraged.*

Summary and recommendations

The main idea behind assigning a registration number to the devices is to provide an unambiguous link between the inventory and the object. Other benefits provided are:

- Unambiguous number code link.
- Provides institution (hospital name) identification.
- Easy to see and read by all user levels.
- Instant link between the device and MEMS for all transactions.
- Provides other info such as; Department, Acceptance date, etc.
- Serial number acts as a redundant link when combined with the type designation.
- Assists departments in keeping control over their equipment.
- Use of different label types can identify different control functions.
- Assists distributors in repair work.

There are many disadvantages as well, perhaps even more, and they can be such as:

- Correct choice of labelling.
- Strong washing solvents.
- Exposure to tough mechanical wear.
- Poor adhesives.
- Object too small for attachment.
- Difficult surfaces, e.g. rough plastics.
- Subjection to high temperatures (autoclaves).
- Fading of text, if poor quality marker pens have been utilised.
- Bad positioning, such as battery lids that may fall off or keypad fronts that have to be replaced.
- Repairs done by supplier where exchange equipment is offered.

- Interference from hospital staff, deliberate removal or exchange of registration labels.

- Inadvertent double numbering (confusion).

As one can see, there are many unfavourable factors suggesting that allocating, marking, and managing registration numbers might make the whole process seem very distasteful. However, if correctly done, the advantages in daily life will be instantly recognised—speed of access to the MEMS being the ultimate prize.

If advice is to be given and taken, then without hesitation, our recommendation will be;

- Do it!

- Use experienced staff only, to constantly control the quality of the registered data. After the system is well established helpers can be trained in giving support. Never use untrained personnel for this kind of work, the consequences of bad data registered in the MEMS is as a virus in a data program.

- Use a non-significant sequential number only. Though it may seem smart to use an significant number, this is not recommended since hospitals are usually quite unstable places—expressed as changing routines, the restructuring of departments, rehousing, etc. Such events will devastate the coding if a significant number is used (figure 47).

- If labelling is not feasible, link through the device's serial number.

- Other desired information can be incorporated into the label.

- Never downgrade this type of work as being petty. If well looked after, a host of high grade information is at your fingertips.

- The verification of devices types must *always* be done by visual inspection of the actual device. Correct information cannot be gathered from brochures, literature, etc.

- Absolute tidiness and great care for detail is absolutely essential in this kind of work.

- A MEMS with protected core information (basic data), and user access control must be considered.

- Affix two identical labels to each device. One that can be immediately seen, for example on the right hand side of main housing/body, as front panels usually are already cluttered with controls and instructions. The other should be affixed in a protected place, e.g. underneath. This routine is recommended by Det norske Veritas (DnV) in their QA handbook, see part *2.06 ACQUISITION §2.06.07.05*.

- Avoid labelling upon difficult plastics, loose lids or covers.

NORWEGIAN STANDARD **August 1991**

English version

Specification of a technical administrative computer based maintenance system for clinical engineering departments.

Introduction

This Draft is the result of a working group with representatives from the clinical engineering departments of the major Norwegian hospitals in Norway and it is proposed issued as a Norwegian Standard.

The background for this Draft is that today several non-compatible systems are used for the administration of medical devices. To avoid further development of conflicting systems, standardization is needed. The need for a standardized classification of medical devices is recognized through the introduction of a hierarchical classification of the device data.

This document is divided in three parts:

- The specification of the technical administrative system.

- An Annex A describing a proposed extension as a guide to an integrated overall solution for a Clinical Engineering Department.

- An Annex B describing a model for a medical device quality system for health care facilities to illustrate the role of the medical device administrative system in a greater context.

  Annex B is identical to a proposal for work items sent the Secretary of CLC/TC 66 April 1991.

Editorial note:

This document is not at the time being in the correct format of an International Standard. The original format of the document is kept to have the philosophy of the original draft more clearly outlined.

ANNEX A

Standard data model

Classification and registration of medical devices

This standard data model describes the minimum requirements for a data system, that should employ the application of the new device codes and take part in the exchange of data. We have chosen a hierarchical classification of the device data to get the most efficient and consistent classification. This is done in three entities, as shown in *figure 2.1*.

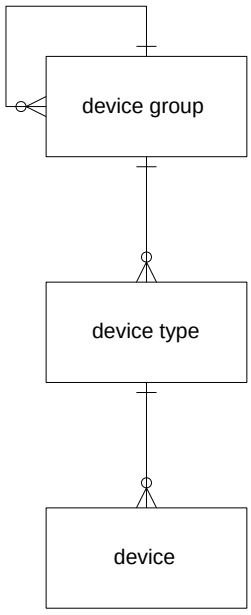


Figure 2.1: Data model for classification and registration of medical devices

Device group is the top level in the hierarchy. The entity describes the main function of the device. For instance:

Infusion, pump pain alleviation
Infusion, pump syringe
Monitoring, bedside unit

The entity enables the application of synonymous Device Groups.

Device Type is the next level and the entity describes the Device Type (or model). For instance:

Hewlett Packard 78342A
IVAC 591 Starflow
Valleylab Force 2

It is at this level in the database model one finds the major deviation compared to most other present systems. It is our intention that the contents of the entities' Device Group and Device Type are standardized and taken care of by a central institution.

Device is the lowest level and the entity describes the physical apparatus with registration number, serial number, localisation, manufacturer, etc.

Description of the entities

Key to the symbols:

Type:

C - Compulsory (is a premise for exchange of data).

R - Recommended/taken care of by the local system.

S - Field maintained/distributed by central institution.

U - Unspecified, i.e. a specification of the format to give the field(s) their desired functionality is not possible/wanted.

I - Interval, i.e. locally generated codes are in the range 1 - 9999, approved codes are > 9999.

Format:

not completed - The format is chosen by the system designer according to existing needs, and within the limits of the database tool.

int - Minimum 32 bit integers.

anum - Alphanumeric, preferably Latin alphabet 1 (ISO 8859/1).

date - dd/mm/yyyy.

price - The format is chosen according to needs, but it should be clearly stated whether the amount includes VAT/sales tax or not.

The concept guide text is introduced so that the field name at the same time is a proposal to a guide text on the user's screen. A guide text in parenthesis is descriptive and should not be stated on the screen. For the reminder the naming within the system is without limits.

Device group:

Guide text	Type:	Format:	Comment:
(Group num.)	CSI	int	Unique
Group	CS	60 anum	
Description	RS	70 anum x 5 (5 lines).	Written description of the device group.
(Reference)	CS	int	If <> 0 this Device Group is synonymous with the Device Group where the group number = this Device Group's reference (recursive relation).

Device type:

Guide text:	Type:	Format:	Comment:
(Type num.)	CSI	int	Unique
(Group num.)	CS	int	Relation to device-group.
Make	CS	60 anum	
Model	CS	60 anum	
Trade name	CS	60 anum	
IEC-class	RS	8 anum	(I, II, III)
IEC-type	RS	10 anum	(B, BF, CF...)
Depreciation	RS	int	Expected life-time/depreciation.
Documentation	RU		Localisation of the documentation.
Manufacturer/ distributor	RU		Recommended implementation: as relations to manufacturer/distributors register(s).

The fields Manufacture, Type and Model are given as stated for distribution of registers. If requested these fields may be combined, for instance, to satisfy demands for a specific search in the database.

Device:

Guide text	Type:	Format:	Comment:
Registration number	CU		
(Type num.)	C	int	Relation to Device Type.
Serial number	C	20 anum	
Date of delivery	C	date	
Delivered by	CU		Recommended implementation is a relation to a manufacturers'/ distributors' register.
Service	RU		Recommended implementation as a relation to contract a service contract register.
Guarantee	RU		
Date of disposal	C	date	
Purch. price	R	price	
State	R		
Part of	CU		Recommended as a relation to an installation register.
Localisation	CU		Recommended implementation as a relation to department register. Actual attributes are building, room number, room name, ward and floor.
Owner	RU		
Financed by	RU		

Registration of device related incidents

Job:

Guide text:	Type:	Format:	Comment:
Registration number	CU		Relation to the number device entity.
Carried out	CU		Recommended implementation as relation to a register of employees.
Description	C	70 anum x 5	Description of what is to be done/ corrected.

Work carried out	C	70 anum x 5	Description of the work done, possibly as a reference to an archive. (Key words: EN46000 and EN29000).
Date of work	C	date	
Type of job	CU		See below
Expenses	CU	price	Cost is used here in a broad sense, the actual attributes are: - Internal/external time used. - Internal/external cost per hour. - Total cost for external services. - Cost of spare parts. - May also be implemented as 1:1 relation to a (internal) invoice register.

In relation to quality assurance, jobs are classified in the following manner:

1. Preventive maintenance (PM).
2. Unforeseen corrective maintenance (UCM). (Maintenance due to defects occurring regardless of the PM).
3. Planned corrective maintenance (PCM). (The plan is to use the equipment until a defect occurs and then correct the defect).

It is required that the **type of job** should identify these classes when reports are made from the system.

Concerning the contents of **description** and **work carried out**, this ought to be registered so that by looking at the first line, one can identify the cause of the work and the work done.

A proposed extension of the standard data model

The recommended data model shown in *figure 3.1* is meant to a guide to an integrated overall solution for a Clinical Engineering Department (CED). The model is adjusted for hospitals of various sizes in such a manner that, with the exception of the standard data model, it is the hospitals themselves that choose which entities (registers) and relations they want to include in their systems. The following description gives a brief explanation of the purpose of the different entities and relations.

Manufacturer/distributor and customer registers

The objective is that the hospitals use a single, norm-based manufacturer register, offered by a central institution. Some hospitals have already established such internal registers and wish to keep them, while others have not yet taken the effort to make such registers. The data model shown in *figure 3.1* suggests a way of organizing these registers. Within the model it is stated who the **manufacturer** of a **Device Type** and **distributor** of a **device** are. "Who deliver what" may be stated in the M:N relation between **distributor** and the **Device Type**. One can state whether the **distributor** also performs the service both in the M:N relation and in the **distributor** entity. **The distributor** and **manufacturer** may also be combined. The difference between them may, if required, be stated in a similar manner.

The entity **customer** may contain an overview of which hospitals, departments/wards and firms one supplies services to, or ordinary customers that are offered rentals. Please note the relation to the **Job** entity.

Applications of the Job entity

In addition to the **Job** entity defined in the standard its functionality ought to be expanded towards a universal booking system. When each employee registers his assignments in the **Job** entity, the data generated give the following options:

- Generation of updated job lists for one or a group of employees.
- Automatic reminder about incomplete jobs.
- Regulation of the workload among the employees by, for instance, changing the job responsibility. A similar application of the system may be done in the regular planning process.
- Follow up interrupted assignments.

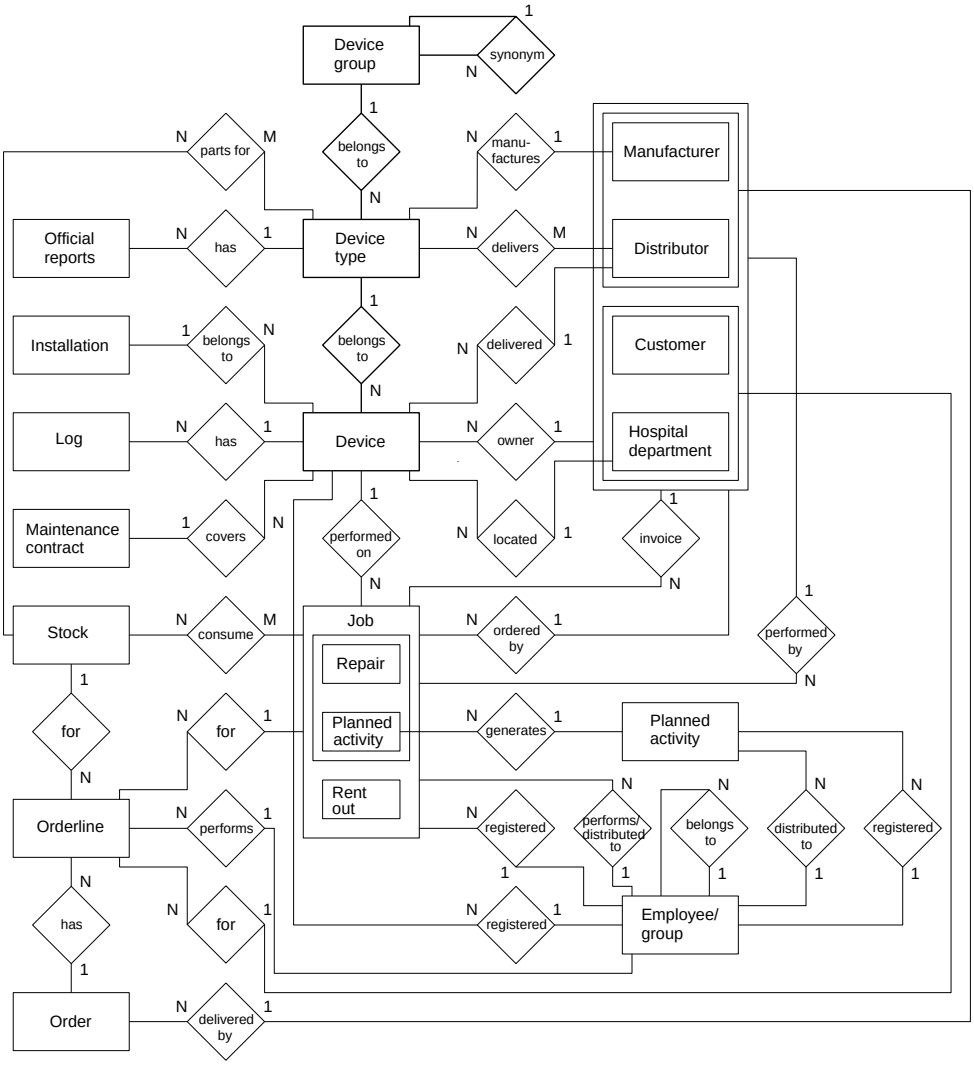


Figure 3.1: The proposed extension of the standard data model

Generally such registration will lead to a greater assurance of actually getting the job done. If a multiterminal data system is applied, rather than a more centralized/manual system, jobs may be registered at all the terminals, and overviews of relevant jobs can be produced at a similar number of places. In a large hospital a secretary may take care of the reception duties and the registration of incoming jobs. Important information for those who do device-related jobs is:

- Identification of the device in question and further information given by the data model shown in *figure 2.1*.
- Contact person/person who has given the assignment.
- Device location.
- When and who received the assignment.

When the job is being registered, identification of the device can be done by means of the device registration number. If the user does not know the registration number at present, good search criteria should be available, thus securing correct identification.

For the registration, each job may be distributed to a member of staff either explicitly by the person doing the registration or implicitly by the system. The latter should be done according to authorizations (not sketched as a relation in figure 3.1) or by letting the system make a suggestion according to a given algorithm.

Some jobs may only be completed within certain time limits, so that the actual time to complete the job must be stated in the job entity. The latter makes it possible to expand the system's functional characteristics so that it contains both an appointment system and a shift-planning system. The concept **job** will then get an expanded meaning compared to the standard data model, and may contain rental, guarantee survey, purchases, perfusion services, meetings, lectures, etc. In addition to the attributes in the **Job**, entity may be the following:

Time of registration.
Type of job (rental/purchase/lecture/meeting/perfusion, etc.).
Contact person/inquirer + telephone number.
Object localisation/Job site.
Planned starting point (date + hour).
Planned finishing point (date + hour).
Urgent (Y/N).
Job status (Finished, postponed, waiting for spare parts, etc.).
Invoice number (If the MDD is charging for the assignment).
Invoice sent (Y/N).
Invoice paid (Y/N).

The different job types will see different samples of the attributes (fields). Figure n gives examples of different types of **Jobs** and the number may be expanded. The main expansion principle is therefore to supply the system with more attributes and establish new samples. The relation **performed on** should be inactive ('nil' or 0) if the **Job Type** suggests that a **Job** is not connected to a **Device**. We can also see from figure x that a **Job** is **registered by** an **Employee/Group**, is **distributed to** an **Employee/Group**, is **given by** somebody and that somebody eventually should be **charged**. A redistribution of a **Job** will then be equal to a change in the relation **distributed to**. If one chooses to redistribute a **Job** that has already been started, the system must be able to accumulate the cost and the time used. In this case the relation **distributed to** must be of the M:N type to secure full traceability. The

entity **Employee/Group** has a recursive relation, which gives us the option to describe the composition of groups within the organization, i.e. which employees that **belong to** which group.

The users often have a need to take out their own job lists or the list for their group/section. These should be sorted according to time of registration, but jobs marked with **urgent = Yes** may be put on top of the list. Jobs that have a stated time limit for completion should be clearly indicated on the list. The information on the job list, produced by the system, is collected from the **job** entity and the standardized entities.

It is important to establish a well reasoned philosophy early on, regarding *which* jobs to be registered in the system, as well as the quantity necessary to describe the job satisfactorily.

Planned (Periodical) Activity

The entity **Planned (Periodical) Activity** (PPA) is a natural extension of the entity **Job**. **PPA** generates **Jobs** from a given date, which should be the date the user gets to know which assignment he/she soon will get, and not the actual date for performing the job (too late). Quality Assurance Procedures for Preventive Maintenance (PM) may be applied in this way. A job of the PM type is normally connected to a **Device** and for the purpose of efficacy it is best to let the **PPA** generate several PMs for more **Devices** of the same **Device type**. At the same time it may be suitable to limit the number of PMs, by for instance choosing the **Hospital department**. Such options are not included as relations in *figure 3.1*, but may be done by putting M:N relations between the **PPA** entity and the entities **Device**, **Device type**, **Device group** and **Hospital department**. Each **Employee/Group** should be given the option to distribute the preventive maintenance on this basis over a period of time. A support system for this feature would be of great importance.

In addition, the users may apply the **PPA** for future (periodical) reminders, like for instance:

- Recalling rented devices (automatic generation of **PPA** for this when the rental is started?).
- Making contact with the users after a certain time, after the repaired device has been returned to check if it still works and so on.
- Postpone a **Job** by moving it to **PPA** and stating a new date when the activity should be on the joblist again.
- Ordering of spare parts, for instance a fortnight ahead of the preventive maintenance.
- Fetching plane tickets, taking backup, paying of invoices, etc.

The attributes in the **PPA** should be able to describe the relevant **Job**. In addition, there is the expiry date and period.

Stock keeping

On *figure 3.1* the entity **Stock** is thought to contain a systematic overview over spare parts and accessories. The M:N relation **spare parts to** states whether spare parts/accessories are connected to certain **Device types**, which is useful when making references. **Consumption** from **Stock** is related to **Job**.

Stock, a **Job** and a **Customer/Hospital department/ward** may require parts/accessories that presently are not to be found in **Stock**. If so, this is noted in the entity **Single orders**. At fairly frequent intervals **Single orders** may be gathered in **Orders** that may be sent, and after a while, result in a delivery by the **Manufacturer**. The attributes in the **Order** entity may, for instance, be the requisition/reference number, date of ordering, date of receipt, etc. Remaining orders may be handled as a recursive relation to **Order**. The signature upon receipt may be done as a relation to the **Employee/Group** entity.

'Log' and 'Public Reports'

In *figure 3.1* several entities are placed on top of each other, each tagged with the name Log. Here bits of information may be stored that relate to the history of a registered device, like accidents, special incidents, measured parameters, etc. A possibility that has to be considered, is to standardize this information at a later stage.

Public reports may be generally useful information about a **Device type**. Such information may be other users' experience with the equipment, an overview of people with special expertise regarding the device in question, frequent defects with suggested solutions, and accident reports. Such information may be entered by the hospital, but it would be useful if many institutions distributed such information. It would also be relevant here to think of standards.

ANNEX B (Informative)

Quality assurance in health care facilities

Introduction

The technical revolution in patient care has increased the possibilities for better and extended medical procedures. The hospitals as organizations have however not been able to fully exploit the benefits of the technological development. Based on the experience of ten years of investigations of accidents, the most important reason is the lack of quality system which directly or indirectly causes 30/50 % of the accidents. The following outlines a simple system tested during the last five years at 75 health care facilities.

General description

This system may divided in separate blocks as described below and cover the lifetime of the device starting with the purchasing procedure up to the end-of-life of the device.

The need of input from other CENELEC TC's and/or other standardizing bodies such as IEC, ISO and CEN is recognized.

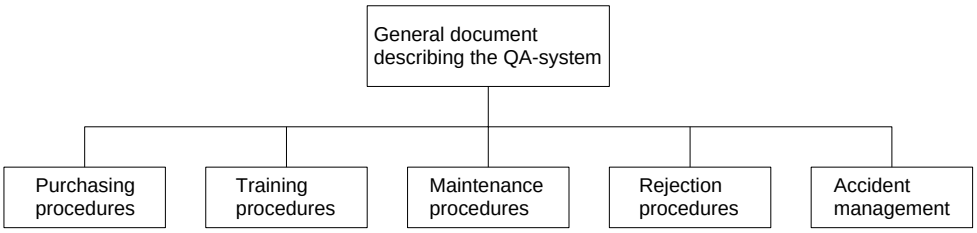


Figure nn:

Purchasing

Aim: To ensure that

- the right kind of (the most suitable) device is selected.
- education and training, if needed, is planned.
- maintenance and operating costs are evaluated.
- the decision is taken whether maintenance is to be performed by the hospital or from outside.

Tools

Checklists.
List of CE-marked devices?

References

IEC 930: *Guidelines for administrative, medical and nursing staff concerned with safe use of medical electrical equipment.*

Acceptance test

Aim: To ensure that

- the deliverance is according to contract.
- no transport damage has occurred.
- the device data are registered.
- parameters to be checked during maintenance is recorded.

Tools

Software for planned maintenance and recording of device history.

References

IEC 930: *Guidelines for administrative, medical and nursing staff concerned with safe use of medical electrical equipment.*
IEC SC 62A: *DIS - Guidelines for maintenance.*
IEC SC 62B: *QA of X-ray.*
NEK-standard: *Specification of technical administrative system for medical engineering departments (Under consideration).*

Training and education

Aim: To ensure that

- operators have the necessary skills in using and maintaining the device.
- clinical engineers has sufficient skill to maintain the device.
- operators skills are maintained and that training.
- education of new operators are performed.

Tools

Accompanying documents.
Supplementary educational materials.
Simulator training programs.

References

COMMETT project 5247: *Development of a general training module for quality assurance in medical technology.*
IEC SC 62A: *DIS - Guidelines for the development and use of medical device educational materials.*
IEC SC 62A: *DIS - Guidelines for the use of hf surgery equipment.*
IEC SC 62A: *DIS - Guidelines for the use of cardiac defibrillators.*

Maintenance

Aim: To ensure the safe and proper functioning of the device and reduce the time between failures.

Tools

Technical administrative system for planned maintenance, recording of device history.

References

IEC 930: *Guidelines for administrative, medical and nursing staff concerned with the safe use of medical electric equipment.*
IEC SC 62A: *DIS - Guidelines for maintenance.*
IEC SC 62B: *QA of X-ray.*
NEK-standard: *Specification of technical administrative system for medical engineering departments (Under consideration).*

Handling of accidents

Aim: To ensure that accidents are handled according to national regulation and the facility's internal routines.

Tools

Checklists.

References

Norwegian National Regulations.

Rejection and change in use

Aim: To ensure that

- devices not longer fulfilling the safety requirements are rejected and destroyed.
- devices which are replaced by new ones are evaluated to decide if the may be used for e.g. less advanced medical procedures.

Tools

Device history record from the maintenance system.

Terminology and international standards

In the work "*Categories*", Aristotle gives definitions to "*primary and secondary substances*" which are equivalent to our Device Group and Device Type levels. Many definitions in the standards on terminology are based on the works of Aristotle. In the following is quoted relevant definitions from some of the most important ISO standards.

ISO 704 Principles and methods of terminology (1987)

3.1. **Concepts and objects.**

Concepts are mental constructs serving to classify individual objects* of the inner or outer world by way of more or less arbitrary abstraction.

* individual object: Phenomenon of the outer or inner world which is observed (or can be observed) by man at a given moment.

Term: Word or phrase used to designate a concept.

3.2. **Characteristics.**

Characteristics serve as a basis for the classification of concepts. They are necessary for the differentiation of a concept from other concepts of a specific field and for other function as well.

For the creation of new concepts in certain applied fields *intrinsic* characteristics as shape, size, material or colour are used in preference to *extrinsic* characteristics, such as origin, function, location, discoverer, inventor, position.

Characteristics can also be subdivided into *essential* characteristics and *inessential* characteristics. Essential characteristics are those characteristics which reflect the essence of an individual object in a specific field according to a given point of view.

NOTE: The distinction between essential and inessential characteristics depends on the purpose of the terminological work.

An individual object can be seen by different disciplines from different points of view which gives rise to the formation of different concepts representing the same individual object.

The standard also gives definitions to different kinds of relationships and definitions, system of concepts and system of terms.

ISO 1087 Terminology – Vocabulary (1990)

2.1. object: Any part of the perceivable or conceivable world.
NOTE: Objects may also be material (e.g. engine) or immaterial (e.g. magnetism).

3.2. concept: A unit of thought constituted through abstraction on the basis of properties common to a set of objects.

3.2. characteristic: Mental representation of a property of an object serving to form and delimit its concept.

3.6. class: Totality of all objects to which a concept refers.

3.10. system of concepts: Structured set of concepts established according to the relations between them, each concept being determined by its position in this set.

5.3 **Representation of a concept.**

5.3.1 **designation**: Any representation of a concept.

5.3.1.1 **symbol**: Designation of a concept by letters, numerals, pictograms or any combination thereof.

5.3.1.2 **term**: Designation of a defined concept in a special language by a linguistic expression.
NOTE: A term may consist of one or more words [i.e. simple term, or complex term] or even contain symbols.

5.3.1.3 **name:** Designation of an object by a linguistic expression.

5.6.1 **preferred term**: Term recommended by an authoritative body.

5.6.2 **admitted term**: Term accepted as a synonym for a preferred term by an authoritative body.

5.6.3 **deprecated term; rejected term**: Term rejected by an authoritative body.

5.6.4 **obsolete term**: Term which is no longer in use.

5.2 nomenclature: System of terms which is elaborated according to pre-established naming rules.

The ISO 1087 is very useful for naming the different concepts in a nomenclature.

ISO 10241 International terminology standards — Preparation and layout (1992)

This standard uses the definitions given in *ISO 1087*. The *ISO 704* is referred to for formulation of definitions and underlying principles.

The following is the most important our work:

6.1. Types of terminological data

For standardization purposes, the entry shall contain at least

a) the entry number;
b) the preferred term representing the concept;
c) the definition of the concept.

Additional information of the following kinds may have to be added:

d) pronunciation;
e) abbreviated form;
f) full form, when the preferred term is an abbreviation;
g) symbol;
h) grammar;
i) subject field;
j) reference to source;
k) non-preferred term(s) (admitted, deprecated, obsolete, superseded);
l) other representation(s) of the concept (e.g. formula, figure);
m) reference to related and other entries;
n) example(s) of term usage;
o) note(s);
p) equivalent terms in other languages.

ISO/IEC DPTR 9789 Coding methods and principles

Draft proposal *ISO/TR 9789 Coding methods and principles* describes different principles and possibilities for codes that may concern the NKKN nomenclature:

> When designing data models for data processing systems and the coded representation needed for their registration, *the objectives of the user* will determine the choice of the entities or attributes to be taken into account as well as their interrelationship. The methods to be used for identification, classification or referencing will depend on those objectives.
>
> (The *italicised* text applied by authors.)

> **Entity**: Any concrete or abstract thing of interest, including associations among things.

> **Classification**:
>
> The purpose of classification is to group entities or attributes in accordance with pre-determined characteristics based on which similarities can be ascertained. Classification is often used to support decision making or to get insight in trends of development, without having to examine each entity or attribute separately.
>
> So, classification can be defined as:
>
> A systematic arrangement of entities or attributes in groups or categories based on the similarity of predetermined characteristics.

> **"Miscellaneous" category**:
>
> A code category for "*Miscellaneous*" or "*Other*" must be used with great discretion. One should not allow the placement of entities in this category which actually belong in a more specific class. (6.5.5.)

- 2.3 KEY TO FURTHER INFORMATION

  Reference number and is needed as a key to further information. The key in itself is meaningless, but gives access to the data required.

- 2.4 FURTHER INFORMATIONS

  Identification is done by means of systematic registration of intrinsic characteristics, i.e. those characteristics which are inalienably part of an entity or attribute.

Example: dimension, weight, colour, voltage of a product.

(*NB*! It is strange that the examples given here are exactly the kind of characteristics that we discarded as being frugal.)

- 3.1 FORMS OF DATA CODE

  ...many code structures applied in practice are often combinations of these basic types.
  1. Non-significant.
  2. Significant.

- 3.2 SEQUENTIAL CODES

  3.2.1 Data items to be coded are assigned a number taken sequentially from an ordered set of numbers. These numbers are mostly natural integer numbers but alphabetic numbers may also be used, ...

  3.2.4 Use

  Sequential codes are generally used as self contained codes for identification or referencing purposes, or as part of a composite code, often in addition to a classifying code.

  3.2.6 Types of sequential codes

  There are three basic types of sequential codes:
  - incremental;
  - group;
  - arranged.

3.2.6.1 Incremental sequential codes

Items to be coded are assigned a code value determined by increasing the previously assigned code value by 1 (or 2 in case of even numbers, or 10 if only multiples of 10 may be assigned).

With this method a code value does not express any meaning. Similar items are not grouped. The rationale for assigning code values other than increasing by 1 can be the requirement to use the intermediate code values for subsequent modifications of the original coded item.

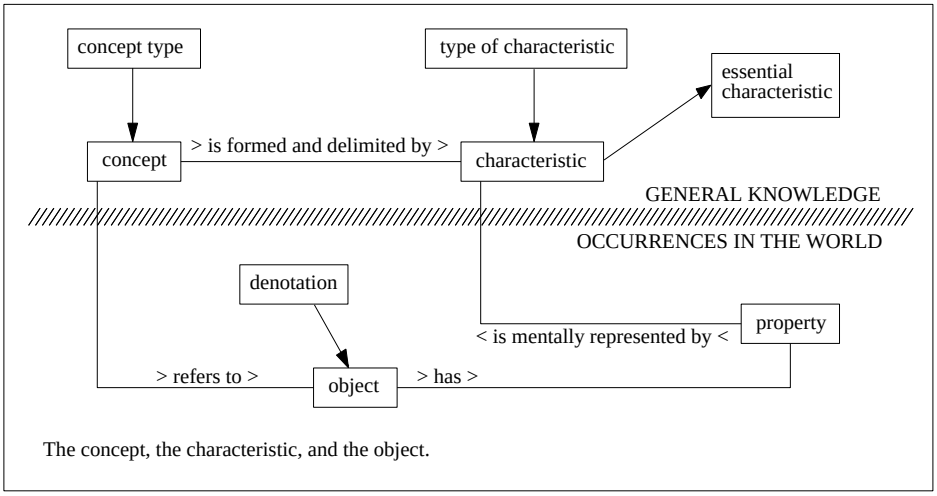
- 4. FEATURES OF CODES
- 4.2 UNIQUENESS
- 4.3 EXPANDABILITY
- 4.4 CONCISENESS
- 4.5 SIMPLICITY
- 4.6 VERSATILITY
- 4.10 SIZE

Code values of a variable number of characters have two major drawbacks:

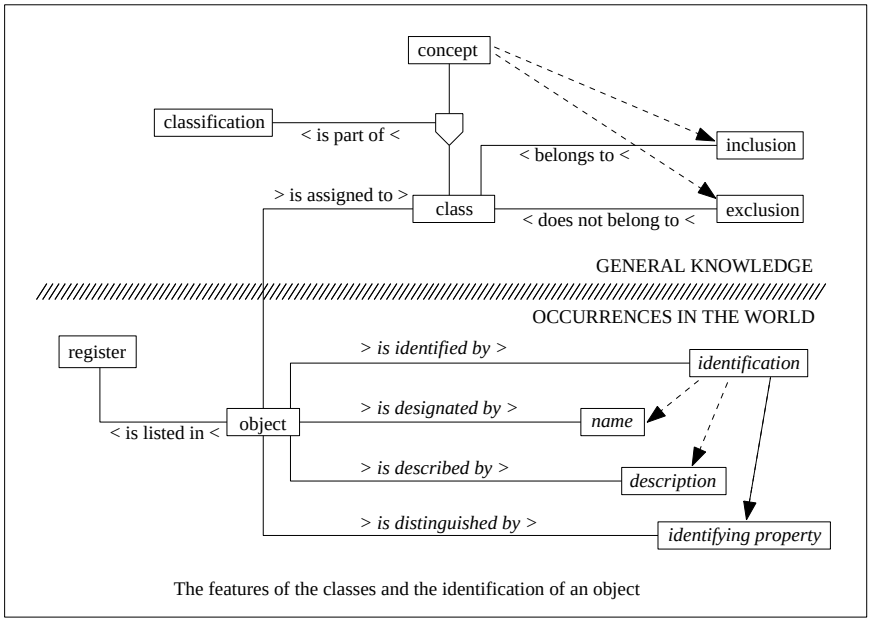
1. The number of characters is unpredictable which may give rise to justification problems, when storing the code value in a data field which accommodates more characters than used for the code value. Data may either have to be "*left justified*" or "*right justified*" or to be aligned on a decimal sign. Left and right justification errors are common in data entry (field shift). The incorrect ...

2. Errors due to omission or addition of characters cannot be easily detected either by humans or by machines. The uncontrolled addition of prefixes and/or suffixes to an original code value is a general and often occurring problem. As prefixes and suffixes mostly are of a variable nature and will not always be present, this will easily give rise to wrong interpretations and errors. For these reasons code values with a fixed number of characters are recommended.

PT003 MOSE



Characteristic (PROJECT TEAM, PT003 MOSE, 1992)

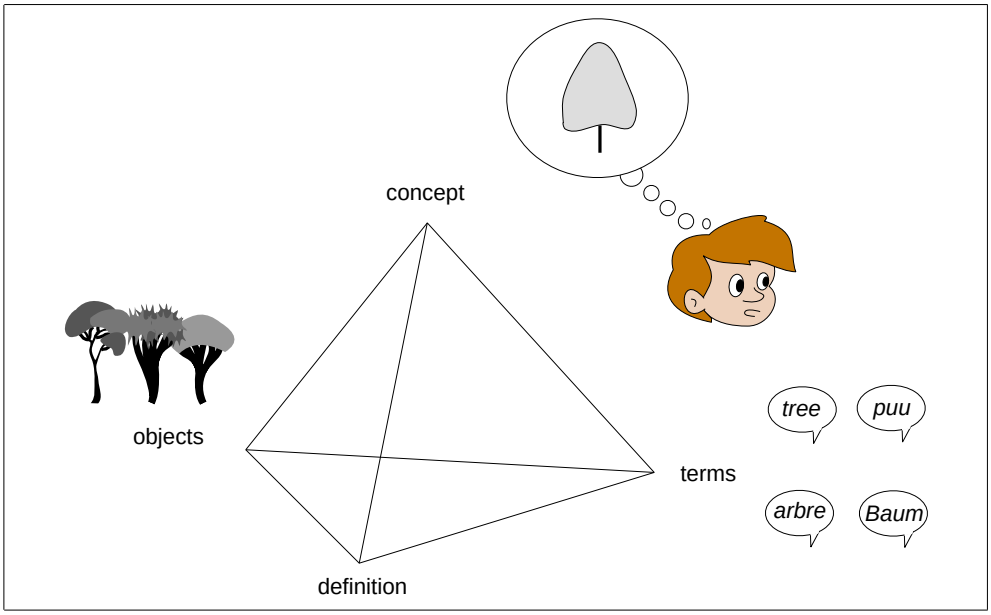


Register (PROJECT TEAM, PT003 MOSE, 1992).

Node label: (PT003 MOSE, Annex H, 3.1.)

Term of a thesaurus that designates a dummy pragmatical node.
NOTE: It applies to place holder and clusters, provided just to explain the hierarchical relations, i.e. terms that may not be used in any application.

Object, concept, definitions and term



Relations between object, concept, definitions and term.

[Source: Tekniikan Sanastokeskus, Finland]

References

(1) *Medical Devices Directive*, CEC 14 June 1993.

(2) Ofstad, Jarle et.al. (1982): *Kontroll av Medisinsk-teknisk utstyr*, NOU 1982:8, Oslo.

(3) FEB (1991): *Forskrifter for elektriske bygningsinstallasjoner m.m.*, Norges Vassdrags- og Energiverk, Oslo.

(4) NKKN: *Medisinsk-teknisk utstyr - Apparatgrupper*, 1. utgave, Det Hvite Huset, Bergen 1993.

(5) IEC 601-1: 1988 (EN60601-1), *Medical Electrical Equipment, Part1: General requirements for safety*, International Electrotechnical Commission, 1992.

(6) NKKN: *A Common European Nomenclature and Coding System for Medical Devices*, Bergen, Aug. 1993.

(7) Jensen, Grimnes: *Elektromedisinsk Utstyr, Utvalgte emne og apparater*, Medisinsk teknisk avdelings forlag, Oslo 1987.

(8) *Apparecchiature Biomediche, Ditte Produttrici, Modelli*, Annuario 1992 - 1993, Area per la Ricerca, Trieste.

(9) United Nations System, *United Nations Common Coding System (UNCCS)*, February 1993.

(10) NATO nomenclature (FSMK 1973, and NAVF 1975 and 1980).

(11) FDA nomenclature (USA).

(12) AIM/BEAM project: Deliverable no. 03, *Design of the Medical Device Coding and Classification System.*

(13) *Universal Medical Device Nomenclature System (UMDNS), 1992 Product Categories Thesaurus*, ECRI, Plymouth Meeting, PA 19462, USA.

(14) *Artikelkatalog Krankenhaus, Katalog Medizintechnik*, 1991, emtec e.V., Berlin.

(15) Dr. A.R.P. Smith: *Medical Device Coding, A Short Review*, Dec. 1990, London.

(16) *IT-plan for forvalningen, Felles vareklassifiseringsystem i staten*, Statskonsult, Oslo 1994.

(17) prEN 46002, *Quality systems - medical devices - particular requirements for the application of ISO 9002*.

(18)‡ Draft proposal ISO/IEC DPTR 9789 (1989-06-12), *Guidelines for the organization and representation of data element types for data interchange - Coding methods and principles*. (ISO/IEC JTC 1/SC 14)

(19)† ARBEIDSGRUPPEN: Rapport - *Standard spesifikasjon for teknisk-administrativt datasystem for Medisinsk tekniske avdelinger*, Trondheim 1991.

(20) ISO 9999: 1992 (E/F), *Technical aids for disabled persons; classification*, International Organization for Standardization, 1992.

‡ PROJECT TEAM PT003 MOSE (Angelo Rossi Mori), *Model for representation of semantics in medicine*. CEN/TC251/PT003 N34, CEN/TC251/WG2/N 96 a (vers. 1.1 interim document, 1992).

In addition the following books and catalogues have been used:

‡ ISO 704: 1987(E), *Principles and methods of terminology*. International Organization for Standardization, 1987.

Aristotle: *The Categories, On Interpretation, Prior Analytics*, (translated by H.P.Cooke and H.Tredennick), Harvard Heinemann, 1983. ISBN 0 434 99325 5.

Grimnes: *Håndtering av medisinsk-teknisk utstyr på sykehus*, Medisinsk-teknisk avdelings forlag, Medinnova RH, Oslo 1991.

ISO 2788-1986 (E), *Documentation - Guidelines for the establishment and development of monolingual thesauri*, Second edition. International Organization for Standardization, 1986.

‡ ISO 10241: 1992(E), *International terminology standards - Preparation and layout*, International Organization for Standardization, 1992.

‡ ISO 1087: 1990(E/F), *Terminology - Vocabulary*, International Organization for Standardization, 1990.

Healthcare Infopack, CEN, December 1992.

†This document is included in Appendix A.
‡Extracts of this document are included in Appendix B.

Abbreviations

AIM	Advanced Informatics in Medicine
BEAM	Biomedical Equipment Assessment and Management
CEC	The Council of the European Communities
CED	Clinical Engineering Department
CEN	Comité Européen de Normalisation (European Committee for Standardization)
MEE	Medical Electrical Equipment
EN	European Norm
EUROMEDIES	EUROpean MEdical Devices Information Exchange System
FDA	Food and Drug Administration
FEB	Forskrifter for Elektriske Bygningsinstallasjoner m.m.
HUH	Haukeland University Hospital
IEC	International Electrotechnical Committe
ISO	International Organization for Standardization
IVD	In Vitro Diagnostics
MDD	Medical Devices Directive
MDVS	Medical Devices Vigilance Systems
ME	Medical Equipment
MEMS	Medical Equipment Management System
NIOM	Nordisk Institutt for Odontologisk Materialprøving (Scandinavian Institute of Dental Materials)
NIS	Norsk Institutt for Sykehusforskning (Norwegian Institute for Hospital Research)

NKKN	Norsk Klassifisering, Koding og Nomenklatur (Norwegian Nomenclature)
NVE	Norges Vassdrags- og Energiverk (Norwegian Authority for Energy and Water resources)
SH	Statens Helsetilsyn (Norwegian Board of Health, since 1.1.1994: National Board of Health)
UMDNS	Universal Medical Device Nomenclature System