Proceedings of the 2007 IEEE 10th International Conference on Rehabilitation Robotics, June 12-15, Noordwijk, The Netherlands

# Compiling a Medical Device File and a Proposal for an International Standard for Rehabilitation Robots

GertWillem R. B. E. Römer and Harry J. A. Stuyt

***Abstract*—Medical devices produced by manufacturers are subject to regulatory review by authorities. Usually, medical devices are developed at universities and other research institutes. This implies that regulatory activities are to be carried out by the designer at these organizations also. And as early as in the research and design phase of the device. Failing to take into account regulatory requirements in the device phase, has shown to be impeding marketing of new devices. This paper presents guidelines on regulations for the designer. Further, the safety of a medical device can be proven by its compliance with recognized standards. Unfortunately, no standard for Rehabilitation Robots exists. This paper proposes the content of such a standard and invites scientists to contribute to it.**

## I. Introduction

Assistive Technology, such as the Rehabilitation Robot ARM [1] are medical devices. Medical devices are subject to regulatory review by authorities, to evaluate (and ensure) the safety of these products. Basically, this implies that the manufacturer of the medical device is obliged to demonstrate– that is proof– the safety and performance of the device.

Compliance with regulations is checked by inspection of the so-called "Technical File" of the medical device, which is to be kept and maintained by the manufacturer. This Technical File must include (not limitative): intended use, design specifications, commented design and manufacturing methods, risk analysis, calculations and verifications of the design specifications (test reports), design considerations, validation of the design specifications (more test reports), labeling, and in some cases the results of clinical tests, and more.

Most of the information, which must go into the Technical File is readily, if not only, available in the design stage of the medical device. In many cases, (new) medical devices originate from universities and other research institutes. After, or at the end of the research phase, the (design of the) device is transferred to the manufacturer. Unfortunately, ensuring compliance with regulations in retrospect, that is after the device is transferred to the manufacturer, has been shown to be a time-consuming and costly exercise. If even possible at all [2,3]. That is, in some cases, where compliance fails, it may require a redesign of the device. Hence, the designer of a medical device should document essential aspects of the design as early as in the development stage. Therefore, and to facilitate the marketing of the device, a scientist must have basic knowledge of regulatory requirements imposed on manufacturers.

While demonstrating the compliance of a medical device with regulatory requirements, (international) standards are helpful. Unfortunately, no standards are available for Rehabilitation Robots.

The aim of this paper is twofold:

(*i*) provide guidelines for scientists to facilitate the compilation information to go into the Technical File; and

(*ii*) propose the content of a safety and performance standard for Rehabilitation Robots.

Therefore, section II provides and overview of regulations applicable in Europe and the USA. Section III provides guidelines for scientists and manufacturers. Finally, section IV proposes the content of a standard specific for Rehabilitation Robots.

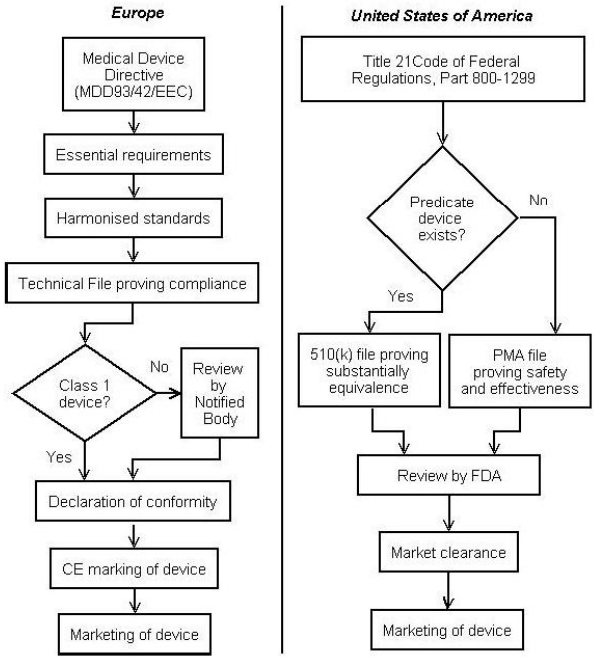


Fig. 1. Simplified representation of the route to market clearance for a Medical Device such as a Rehabilitation Robot, in Europe (left) and the USA (right).

Manuscript received February 4, 2007.

G. R. B. E. Römer (corresponding author) and Harry J. A. Stuyt are with Exact Dynamics BV, Kervel 4, NL-6942 SC, Didam, The Netherlands, phone: +31 316 334114; fax: +31 316 331327 (e-mail: research@exactdynamics.nl).

## II. REGULATIONS

This section describes regulations applicable in Europe and the USA, see Fig. 1. Regulations in other regions of the world are comparable to those in Europe and the USA. In some countries, or regions of the world, clearance to market a medical device is facilitated if clearance has already been obtained in Europe and/or the USA.

### A. Europe

In Europe CE marking, which is an abbreviation of *Conformité Européenne*, is mandatory and must be affixed to any product, by the manufacturer or importer, before it may be placed on the European market. CE marking on a product symbolizes conformity to all the obligations incumbent on manufacturers for the product by virtue of the European Community (EC) directives. The most important EC directive applicable to Assistive Technology such as Rehabilitation Robots is the "Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices" [4], known as the Medical Device Directive (MDD). It covers medical devices defined as *any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease, and/or (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, and/or (iii) investigation, replacement or modification of the anatomy or of a physiological process, and/or (iv) control of conception.* Hence, it not only covers Rehabilitation Robots, but for example also adjustable beds, manual & electrically powered wheelchairs (and their chargers), hoists for the transfer of disabled persons, medical gloves, walking aids, etc. Excluded are, for example, medicinal products (drugs), some active implantable devices, and in-vitro diagnostic devices. For these devices other directives apply.

In the MDD, medical devices are categorized into four Classes. Device classification depends on the intended use of the device and the (potential) risk for the user: Class I (lowest risk), IIa, IIb and III (highest risk). Depending on the device Class, additional regulatory requirements may apply. The devices listed above, and Rehabilitation Robots such as the ARM, are of Class I. Software, which drives a device or influences the use of a device, falls automatically in the same class as the device itself.

EC directives, and the MDD is no exception, define the "essential requirements" (Annex I of the MDD [4]), including requirements regarding protection of health and safety, that goods must meet. Manufacturers are free to choose any method to prove the compliance of their device with the essential requirements. Unfortunately, the essential requirements are formulated in (too) general and global terms. For example: *The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.* Hence, demonstrating (technical) compliance with the essential requirements may prove to be (too) difficult, and therefore costly. Fortunately, the European standards bodies (CEN, CENELEC and ETSI) have the task of drawing up "harmonised standards". Compliance of a medical device using applicable harmonised standards provides legal presumption of conformity to the corresponding essential requirements of the corresponding EC directives. Examples of harmonised standards, related to the MDD are:

- EN 455 Medical gloves for single use,
- EN 1985 Walking aids,
- EN 12184 Electrically powered wheelchairs, scooters and their chargers,
- EN 12523 External limb prostheses and external orthoses,
- EN 12182 Technical aids for disabled persons - General requirements and test methods [5].

A regularly updated and extensive overview of (over 200) harmonised standards, related to the MDD, is maintained on-line by the European Committee [6].

Unfortunately no specific (harmonised) standard exists for Rehabilitation Robotics. Therefore standard *EN 12182 Technical aids for disabled persons - General requirements and test methods* [5] is applicable. Which, for some Rehabilitation Robots, may not completely cover all essential requirements of the MDD. For this reason, the content of a new (international) standard for Rehabilitation Robots is proposed in section IV.

Besides the MDD other EC directives (and corresponding harmonised standards) may apply, e.g. the *Low Voltage* Directive (LVD) 73/23/EEC and the *Electromagnetic Compatibility (EMC)* Directive 89/336/EEC.

Once a manufacturer demonstrated compliance with the essential requirements (probably through harmonised standards) a so-called *Declaration of Conformity* is issued by:

- the manufacturer (Class I devices only) or by,
- an accreditation organization, known as a Notified Body (for Class IIa, IIb, and III devices),

Next, the manufacturer is allowed to fix the "CE mark" on the device and place it on the market.

### B. United States of America

In the United States of America, medical devices are subject to the general controls of the Federal Food Drug & Cosmetic (FD&C) Act which are contained in the procedural regulations in *Title 21 Code of Federal Regulations (CFR) Part 800-1299*. These controls are the baseline re-

quirements that apply to all medical devices necessary for marketing, proper labeling and monitoring its performance once the device is on the market. The governmental organization responsible for carrying out regulatory control regarding medical devices like Assistive Technology is the U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) [7]. Before marketing the device on the US market, the manufacturer must obtain clearance from the FDA, usually referred to as "FDA approval".

The definition of the FDA of a medical device is similar to the European definition (see section II.A). Like is the case in Europe, medical devices are classified based on their intended use and risk. However, the FDA defines (only) three classes (Class I, lowest risk, II and III, highest risk), whereas in Europe four Classes are defined, see Table I.

TABLE I
COMPARISON OF MEDICAL DEVICE CLASSES [8]

| Europe | USA |
|---|---|
| I | I or II |
| IIa | I or II |
| IIb | II or III |
| III | II or III |

Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes. Class III is the most stringent regulatory category for devices, and are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

Unlike the European MDD, classification in the USA is not based on classification rules, but on the basis of finding a matching description of the device in Title 21 of the CFR, Parts 862-892. The FDA has classified and described over 1,700 distinct types of devices (which can be used as *predicate devices*, see below) and organized them in the CFR into 16 medical specialty "panels" [9]. For each of these devices the FDA gives a general description including the intended use, the class to which the device belongs (i.e., Class I, II, or III), and information about marketing requirements. For example, the ARM [1] Rehabilitation Robot is a powered component to be connected to a powered wheelchair. It is therefore classified in the same manner as the powered wheelchair (regulation number 890 (Physical Medicine Devices) 3860, classification product code ITI of the Title 21 of CFR), which is Class II.

One of the differences between the European "CE marking" process and the process of obtaining an FDA approval is the method demonstrating the compliance of the medical device with regulations. In the US, the classification of the device will identify the process the manufacturer must complete in order to obtain FDA approval. This process is either a *premarket notification* (known as a 510(k) submission) or a *premarket approval* (PMA). An PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(r). It usually only applies to Class III devices [15]. A PMA submission is considerably more costly than a 510(k) submission. Assistive Technology, such as Rehabilitation Robot are mainly Class II devices, for which the *premarket notification* 510(k) process suffices. A 510(k) submission is a submission made to FDA demonstrating that the device to be marketed is at least as safe and effective as - that is *substantially equivalent* to - a device that already obtained an FDA approval. The latter device is known as the *predicate device*.

Hence, in a 510(k) file, the medical device is to be compared to one or more similar legally marketed devices, having the same intended use and make to support the *substantial equivalency* claims. The 510(k) file is reviewed by the FDA, and after approval an FDA clearance for the device is provided.

Unlike the European regulations, in which Hamonised standards are prescribed, the FDA has developed extensive Guidance Documents, which relate to [29,11]:

- the processing, content, and evaluation of regulatory submissions,
- the design, production, manufacturing, and testing of regulated products,
- the inspection and enforcement procedures.

Guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Conformance of the medical device with FDA recognized standards is strictly voluntary for a manufacturer. However, conformance of the medical device with standards can provide a reasonable assurance of safety and/or effectiveness [29]. The list of FDA recognized standards is maintained on the CDRH website [12]. Supplemental Information Sheets which, among other things, identifies some or most types of devices to which each standard would ordinarily be expected to apply. In the case of 510(k)'s, information on conformance with recognized standards helps establish the substantial equivalence of the device.

### C. Regulatory differences between Europe and the USA

Table II lists a summary of the main regulatory differences in Europe and the USA.

In the USA, the FDA conducts reviews of the Technical File (510(k) & PMA files) and conducts audits. In Europe, the Ministries of Health collectively have outsourced this task to officially designated the Notified Bodies, such as BSI (United Kingdom), TÜV (Germany) and UL. In Europe, manufacturers of a Class I medical device do not need to have their Technical File reviewed by a Notified Body. Compliance with regulations may be checked by the manufacturer itself and is known as *self-regulation*. Devices in all

other Classes are under regulatory review by Notified Bodies.

TABLE II
SUMMARY OF REGULATORY DIFFERENCES [8]

| | Europe | USA |
|---|---|---|
| Review by: | Notified Body (Class IIa & b, III only) | FDA (All Classes) |
| Classification by: | Classification rules in MDD | Comparison with predicate devices |
| Quality system: | Class I: Recomm. IIa & b, III: Mand. (ISO 13485) | Mandatory GMP |
| Standards: | Harmonised | FDA Guidelines |

Unlike in the USA, European manufacturers are not obliged to implement a Quality System for the design, manufacture, packaging, labeling, storage, installation, and servicing of their medical devices. However, implementing a Quality System is wise. For Class IIa, IIb and III a Quality System is mandatory. In the USA, a Quality System is mandatory for all Classes. There, medical devices require manufacturing in accordance with "Good Manufacturing Practices" (GMP) listed in 21 CFR Part 820 [13]. Both in Europe and the USA the international standard *ISO 13485 Medical Devices – Quality Management Systems – Requirements for regulatory purposes* [14] is recognized as the basis of the Quality System. However, the GMP does prescribe a few additional requirements which are not covered by ISO13485.

Last, but not least, the FDA, besides safety, also reviews the performance and effectiveness claims of the manufacturer, which is less the case in Europe.

## III. GUIDELINES

This section provides some guidelines for scientists and designers at universities, or other research institutes, to ensure smooth transfer of the device design information, which must go, from the designer, into the manufacturers Technical File.

### A. Guidelines for scientists and designers

#### 1) Familiarize yourself with regulations

Unless medical device under development will be marketed in only in one region, scientists and designers of medical devices should familiarize themselves with the nomenclature and basic routes to market clearance applicable in Europe, as well as in the USA. This starts by studying the European Medical Device Directive 93/42/EEC [4] and Guidance Documents of the FDA [29,11]. The next, and most important steps are to classify the device and determine the information which should go into the Technical File [2-4] and/or 510(k) file [29,11]. Relevant information for these files in the design stage includes:

- intended use,
- design specifications,
- design considerations,
- design methods (especially relevant for software developments, see ext sub-section),
- design calculations,
- Risk Analysis (see below),
- verification (of the specifications) and validation (performance, intended use) information.

The information should also include compliance data of applicable standards. Hence, the designer should identify the standards applicable to the device under development [6, 12]. It should be noted that European standards, such as EN 12182 *Technical aids for disabled persons* [5] are not necessarily recognized by the FDA.

Compiling a Technical and/or 510(k) file might seem an administrative burden to the designer– and to some extend it is– but it will also, if not surely, help the scientist systematically develop the new device. That is, in a good design method, this kind of information is documented too. Further, it goes without saying that, proper design documentation, when transferred to the manufacturer, will contribute to a swift market introduction of the device.

#### 2) Carry out a Risk Analysis

An important activity to be carried out during the design phase is Risk Analysis, see Fig. 2. It is an essential and mandatory aspect of medical device regulations, but is unfortunately frequently neglected in the design phase [14,16]. By definition Risk Analysis is *the systematic use and verification of all available information of the device, to identify (potential) hazards of the (design of the) device and to estimate the corresponding risk for the use(rs) of the device.*

Risk Analysis is part of Risk Management, that is, *systematic application of management policies, procedures and practices to the task of analyzing, evaluation and controlling risk*, see Fig. 2. Risk Management as a whole is the responsibility of the manufacturer. Risk Management is governed by the international standard ISO14971 *Medical Devices – Application of Risk Management to medical devices* [17]. No method to carry out Risk Analysis is prescribed by this standard. Methods like the Failure Mode Effect Analysis (FMEA), Fault Tree Analysis (FTA) and Hazard and Operability Study (HAZOP) are frequently used. As are extensive lists of possible hazards, together with contributing factors, which may be associated with medical devices can be used. Further, numerous (technical) protective measures are prescribed by applicable standards, such as in EN 12182 *Technical aids for disabled persons* [5].

For each identified hazard, the design team shall decide, using criteria (pre)defined by the design team itself, whether the estimated risk is so low that risk reduction need not to be pursued. When risk reduction is required, redesign of the device, that is the implementation of (technical) protective measures, is required. Hence, Risk Analysis is to be carried out iteratively during the design phase, see Fig. 2. Carrying

out the Risk Analysis at the end of the design phase, or even after the transfer of the device to the manufacturer, proved to be a time-consuming and costly exercise, if even possible at all. That is, because Risk Analysis may reveal that the device must be redesigned to include the protective measures.

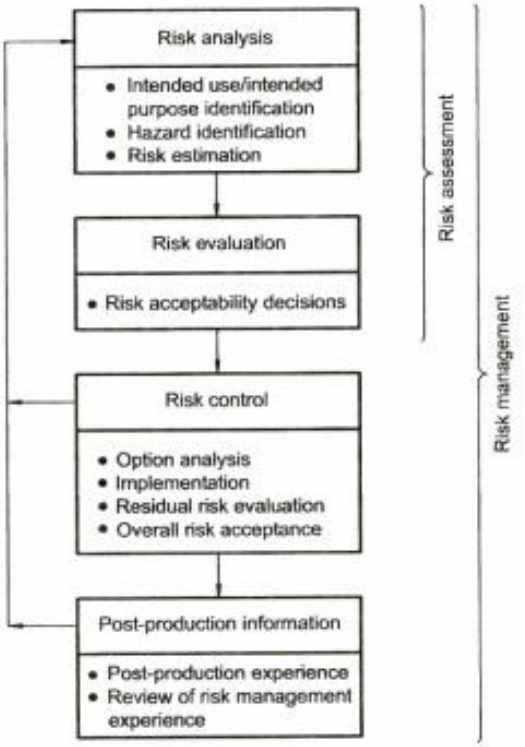


Fig. 2. Risk Analysis is part of Risk Management [17].

*3) Thoroughly document your software design method*

As was mentioned in section II, software, which drives a device or influences the use of a device–which for advanced Rehabilitation Robot will likely be the case–falls automatically in the same regulatory Class as the device itself. The software plays often a critical-safety role in the medical device. Regulatory Authorities state that the level of complexity introduced by the software in a medical device, implies that systematic failures can escape practical limits of testing. That is, testing of (the software of) the finished device, by itself, is not adequate to address the safety of the software, nor of the device. Therefore, more than is the case of mechanical and electronic aspects of the design, requirements regarding the *methods* and *processes* used to design, develop and test software are imposed on manufacturers. Fortunately the IEC standard 60601-1-4 *Medical Electrical Equipment – Part 1-4* provides tools to meet the requirements imposed on software development [18]. For example, Roderick and Carignan describe their approach to designing software safety systems for their Rehabilitation Robot [19].

### B. Guidelines for manufacturers

Of course, the above guidelines applicable to scientists and designers of medical devices at universities and the like, do also apply to manufacturers. One additional guideline, or rather tip, for manufacturers considering acquiring a device design from a university, is not only to asses the (technical and functional) advantages or disadvantages of the new device or prototype. The manufacturer should also carry out a *due diligence* with respect to the technical documentation of the design. Due diligence is a common process of investigation, normally performed by investors, into the details of a potential (financial) investment, such as an examination of operations and management and the verification of material facts. When applied to gaining the rights to the (design of the) medical device it implies the examination and assessment of the (concept of the) Technical File, 510(k) or PMA file.

## IV. Safety & Performance Standard

Currently, no performance and safety standards exists, nor are under development at standard bodies such as ISO, CEN and IEC, to cover specific aspects of Rehabilitation Robots. Many, but not all, safety aspects of Rehabilitation Robots are covered by, for example, *EN 12182 Technical aids for disabled persons - General requirements and test methods* [5]. Nor does any standard cover the *performance* of Rehabilitation Robots. Therefore, this section proposes the content of a standard for Rehabilitation Robots and invites professionals to contribute to it.

### A. Safety aspects

In the ISO (safety) standard ISO 10218, Part 1 *Robots for industrial environments - Part 1* [20], the first line of defense in robot-safety is to enforce segregation, e.g. by a cage, between live industrial robots and humans. An industrial robot differs clearly with a Rehabilitation Robot in the kind interaction with the user (who themselves have highly restricted motion), as well as in the intimacy of the contact. So ISO10218 Part 1 can not be applied to Rehabilitation Robotics.

Basic safety requirements such as protective measures to ensure electrical safety, electromagnetic compatibility, inflammability, biocompatibility, software safety, and the like, are covered by EN12182 *Technical aids for disabled persons* [5] or referred standards in EN12182. Although it provides guidance (although no normative requirements) to prevent ulcers caused by pressure and/or shear forces, EN12182 does not cover an essential characteristic of a robot. Quoting one of the godfathers of Rehabilitation Robotics, Hok Kwee: *"A safe manipulator is a manipulator that does not move"* [21]. Implying that the risk, which is associated with a moving robot, is the risk of injuring, bruising or wounding its user.

It would be tempting to prescribe all kinds of technical protective measures in a new standard for Rehabilitation Ro-

bots, such as slip-clutches, proximity sensors, force sensors, as Risk Control measures (Fig. 2). This would be, however, restrictive and impeding for future technical (safety) innovations, as well as for the creative design process of Rehabilitation Robots.

Therefore, developing safety requirements must start by determining acceptable physiological levels (or criteria) preventing injuring, bruising or wounding the user. Two such studies were cited by Tejima [22,10]. From these physiological levels, limits for the robot can be determined. That is, both the maximum *static,* as well as *dynamic* force the robot may exert on the body of the user. The dynamics force, in turn, may be limited by limiting the maximum kinetic energy associated with the moving robot including its payload.

A first approach was presented by several authors, such as Tejima et al. [22-24]. Although not specifically aimed at Rehabilitation Robots, Ulrich et al. propose a similar approach [25]. They categorized potential injuries to different parts of the human body, and derived maximum allowable loads on the human body, based on models of kinetic energy of the robot's linkages and payload. Unfortunately, they assumed that humans in the workspace of the robot are wearing protective gear. Further, Ulrich et al. also studied methods to explore a trade-off between safety and performance of a robot, see the next section and Fig 3.

If consensus could be reached among Rehabilitation Robotics professionals, the safety requirements based on kinetic energy metrics and contact forces, could be a convenient way to prove the intrinsic safety of these devices, as well as rules for Target Oriented Design [30] of new devices.

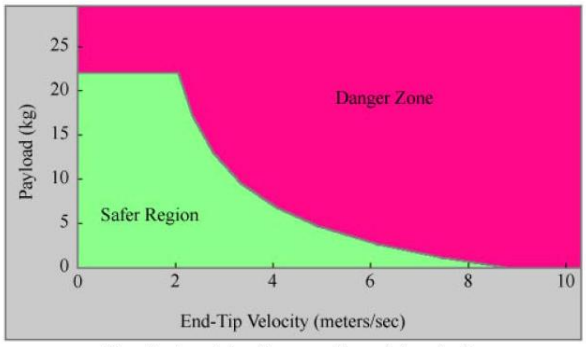


Fig. 3. A safety diagram for a telerobotic system with a safety envelope indicating the region of safer robot design [25].

Professionals in Rehabilitation Robotics are invited to comment on this safety approach, and are invited to participate in the development of a standard for Rehabilitation Robotics.

### B. Performance

Again, available industrial standards, like ISO 9283 *Manipulating industrial robots - Performance criteria and related test methods* [26], can not be adopted for Rehabilitation Robots. This standard describes methods of specifying and testing performance characteristics like; accuracy and repeatability; pose stabilization time; path accuracy and path repeatability etc., which are of less importance to Rehabilitation Robots.

Rehabilitation Robots are complex mechatronic devices. The technical characteristics and specifications, such as the number of degrees-of-freedom (DOF's), accuracy, repeatability, power consumption, etc. of these devices differ considerably. In addition the variety of the devices which come under the heading of rehabilitation robotics is high. Due to this (technical) variety it is not possible, nor desirable to compare the performance on the basis of technical specifications (only). Therefore, a user centered performance criterion for Rehabilitation Robotic was proposed in previous work [27]. It was stated, that the efficiency, and user-satisfaction, of a Rehabilitation Robotic follows from the time needed to complete tasks. In other words "if a rehabilitation robot allows tasks to be carried out quickly, it is a good robot". The Task-Completion-Time, as a performance criterion, is indeed an objective and generic criterion as it also captures, incorporates and covers technical aspects like accuracy and controllability, and also covers hard to quantify characteristics like user-friendliness, ease of operation, effectiveness of input-devices, versatility and cognitive load of the user. It should be noted that a rapidly completed task does not necessarily mean that the robot has to move fast. Characteristics like user-friendliness, ease of operation, effectiveness of input-devices also imply a swift task completion, even when the robot is "slow".

However, as was discussed in the previous sub-section, fast robots are potentially unsafe. Designing a much faster, and therefore a "more efficient" Rehabilitation Robot is relatively simple, by merely implementing more powerful motors. Safety is a pre-requisite for the use of a rehabilitation robot. Therefore, a method, like the one proposed by Ulrich et al. [25], optimizing the trade-off between can (and must) used while optimizing the Task-Completion-Time.

Another improvement to the performance criterion (Task-Completion-Time) of Römer, Driessen and Johnson [27] addresses the problem of relative character of their performance index. That is, their performance index $P_j$ compares the Task-Completion-Time of one robot to the other:

$$P_j = \frac{m_j}{n^2} \sum_{i=1}^{n} \frac{\min\{t_{i1}, t_{i2}, \cdots, t_{ik}\}}{t_{ij}} \times 100\% \qquad (1)$$

where, $P_j$ denotes the (relative) performance quantity of the $j^{th}$ robot, when considering $k$ robots ( $j \le k$ ), $n$ the number of defined/evaluated tasks, $m_j$ number of defined tasks the $j^{th}$ robot can successfully complete ($n \ge m_j$). Further $\min\{t_{i1}, t_{i2}, \ldots, t_{ik}, \}$ is the time it takes the fastest robot to complete task $i$. And finally, where $t_{ij}$ denotes the time it takes robot $j$ to complete task $i$.

To obtain an absolute, rather than a relative, performance index, the Task-Completion-Time of a robot could be compared to the time it takes a *human* to complete the task(s).

That is, the numerator of equation (1) could be replaced by $\tau_i$, which is the time it takes a human to complete task $i$ and the absolute performance index of a robot should be reformulated as (assuming that a human is always faster in completing a task than a robot):

$$P = \frac{m}{n^2} \sum_{i=1}^{n} \frac{\tau_i}{t_i} \times 100\% \qquad (2)$$

where $n$ denotes the number of defined/evaluated tasks, $m$ number of defined tasks the robot can successfully complete ($n \geq m$), and $t_i$ the time it takes the robot to complete task $i$. Table III list some measured Task-Completion-Times of the ARM (Fig. 3), the Raptor [28] and a non-handicapped person, as well as the corresponding performance indices.

TABLE IIII
TASK-COMPLETION-TIME AND
AND ABSOLUTE PERFORMANCE INDEX (2)

| Task | ARM ($m$=2) | Raptor ($m$=2) | Non-disabled person |
|---|---|---|---|
| Operate light switch twice | 30s. | 420 s. | 4 s. |
| Grab cup, take sip, and return it | 60 s. | 300 s. | 4 s. |
| $P$ ($n$=2) | 10% | 1% | 100% |

Fig. 2. Assistive Robotic Manipulator (ARM) [1].

Professionals in Rehabilitation Robotics are invited to comment on this performance index, and are invited to participate in the development of a standard for Rehabilitation Robotics.

## V. CONCLUSION

Scientists and designers of medical devices, such as Rehabilitation Robots should document information on the design of the device for the regulatory Technical File and/or 510(k) file. The proposed content of a standard on the safety and performance for Rehabilitation Robots was based on the kinetic energy, contact force and Task-Completion-Time.

## REFERENCES


[1] G. R. B. E. Römer, H. J. A. Stuyt and A. Peters. Cost-Savings and Economic Benefits due to the Assistive Robotic Manipulator (ARM). *Proceedings of the 2005 IEEE 9th International Conference on Rehabilitation Robotics*, June 28 - July 1, 2005, Chicago, IL, USA, pp. 201-204.

[2] A.W. van Drongelen, B. Roszek, E.A.E. van Tienhoven, R.E. Geertsma, R.T. Boumans and J.J.A.M. Kraus, "AnnexII Technical Documentation Assessed", *Medical Device Technology*, vol. 16, no. 10, pp. 21-23, Dec. 2005.

[3] M. Donawa, "Organising European Technical Documentation to avoid duplication", *Medical Device Technology*, vol. 17, no. 3, pp. 29-31, Apr. 2006.

[4] Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. Available through: http://europa.eu.int/eur-lex/ and http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:NOT (Both accessed January 27th, 2007).

[5] EN 12182 Technical aids for disabled persons- General requirements and test methods, 1999.

[6] Overview of harmonised standards related to the European Medical Device Directive 93/42, available through http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html (Accessed: January 20th, 2007)

[7] U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), http://www.fda.gov/cdrh/ (Accessed: January 26th, 2007).

[8] T. Lopes. *Medical Devices, USA, Canada, EU.* Presentation at the workshop "CE-certification and FDA Approval", Health Valley, Nijmegen, the Netherlands, October 12th, 2006.

[9] http://www.fda.gov/cdrh/devadvice/3131.html (Accessed: Feb. 9th 2007).

[10] M. Nokata and N. Tejima, "A safety strategy for Rehabiliation Robots" in *Advances in Rehabiliation Robotics*, LNCIS, vol. 306, Z.Z. Bien and D. Stevanof, Ed. Heidelberg: Springer, 2004, pp. 177-185.

[11] FDA. Annual Comprehensive List of Guidance Documents at the Food and Drug Administration. January 5, 2005, Volume 70, Number 3. Avaliable through http://www.fda.gov/cdrh/guidance.html (Accessed January 31st ,2007).

[12] List of FDA recognized standards on the CDRH website is available through http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm (Accessed February 1st, 2007).

[13] *21 CFR Parts 808, 812, and 820 Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation*. FDA. Available through http://www.fda.gov/cdrh/comp/gmp.html (Accessed February 1st, 2007).

[14] ISO 13485 Medical Devices – Quality management systems, 2000.

[15] M. Donawa. "Strategic planning for US Premarket Approval submissions", *Medical Device Technology*, vol. 17, no. 7, pp. 21-23, Sep. 2006.

[16] M. Donawa, "Effectively incorporating Risk Management into Quality Systems", *Medical Device Technology*, vol. 17, no. 5, pp. 28-30, June 2006.

[17] ISO 14971 Medical Devices – Application of Risk Management to medical devices, 2000.

[18] IEC 60601-1-4 Medical Electrical Equipment – Part 1-4: General requirement for safety – General standard: Programmable electrical medical systems, 1999.

[19] S. N. Roderick and C. R. Carignan. An approach to Designing Software Safety Systems for Rehabilitation Robots. *Proceedings of the 2005 IEEE 9th International Conference on Rehabilitation Robotics*, June 28 - July 1, 2005, Chicago, IL, USA, pp. 252-257.

[20] ISO 10218-1 *Robots for industrial environments - Safety requirements - Part 1: Robot*, 2006.

[21] Statement of Hok Kwee at a session organised by World Rehabilitation Fund, shortly after the 1986 RESNA conference, where he presented the paper "SPARTACUS and MANUS: telethesis developments in France and in the Netherlands." In: R. Foulds (ed.): *Interactive robotic aids - one option for independent living: an inter-national perspective*. Monograph 37, World Rehabilitation Fund, New York, 1986, pp. 7-17. Private communication.

[22] N. Tejima: "Design method for safe rehabilitation robots", *Integration of Assistive Technology in the Information Age*, pp.346-351, IOS Press, 2001.

[23] *N.* Tejima and D. Stefanov. Fail-Safe Components for Rehabilitation Robotis – A Reflex Mechanism and Fail-Safe Force Sensor. *Proceedings of the 2005 IEEE 9th International Conference on Rehabilitation Robotics*, June 28 - July 1, 2005, Chicago, IL, USA, pp. 456-460.

[24] N. Teijima, T. Akioka, S. Kimura and K. Araki, "Rehabilitation Robot Risk Reduction by three-dimensional force limitation and reflex mechanism". *Proceedings of the 2003 8th International Conference on Rehabilitation Robotics*, April 22-25, 2003 Daejon, Korea, pp. 13-15.

[25] K.T. Ulrich, T.T. Tuttle, J.P. Donoghue and W.T. Townsend, *Intrinsically safer robots*. Barret Technology Inc., Cambridge MA, USA, 1995.

[26] ISO 9283:1998 Manipulating industrial robots - Performance criteria and related test methods.

[27] G. R. B. E. Römer, M. Johnson and B. Driessen. Towards a performance benchmark for rehabilitation robots. *Proceedings of the 1st International Conference On Smart homes & health Telematics* (ICOST2003), Paris, France, September 24 –26, 2003, pp.159-164.

[28] R .M. Mahoney. "R.M. The raptor wheelchair robot system". *Proceedings of the 2001 International Conference on Rehabilitation Robotics*, Evry, France, April 25-27, 2001.

[29] *Guidance for Industry and for FDA Staff; Use of Standards in Substantial Equivalence Determinations* U.S. Department Of Health And Human Services Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluation, 2000. Available on-line at http://www.fda.gov/cdrh/ode/guidance/1131.html (Accessed February 31st ,2007).

[30] P. H. Chang, H. Park, J. Park, J. Jung, B. Jeoon, "Development of a robotic arm for handicapped people: A Target-Oriented Design Approach", In *Integration of Assistive Technology in the Information Age*, IOS Press, Amsterdam, 2001 pp.84-92.