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Designing Actuated Medical Robots for Safe Human Interaction – a Real Challenge

Helga SILAGHI[1], Claudiu-Raul COSTEA[1], Liliana Doina MĂGDOIU[1],
Marius SILAGHI[2], Tiberiu BARABAS[1], Simona-Veronica ABRUDAN CACIORA[1]
[1]Control Systems Engineering and Management Department, University of Oradea, Str. Universităţii no. 1, Oradea, Romania.
[2]Electrical Engineering Department, University of Oradea, Str. Universităţii no. 1, Oradea, Romania
E-mail: hsilaghi@uoradea.ro, ccostea@uoradea.ro, lili34aana@yahoo.com, masilaghi@uoradea.ro, tbarabas@uoradea.ro, veronicaabrudan@yahoo.com

Abstract - ***The paper studies the influence of human factor and clinical constraints specific to mechanical devices for medical purpose. environment (with a limited workspace, inside or outside the patient body). A medical robot is usually a complex system including mechanical structure, human-machine interface (HMI), electronic components, and software controller. All these components are integrated to perform various tasks for daily medical applications. Because any failure may become very critical, medical robots must function safely and with high reliability, so that designing medical robots for safe human interaction can be considered a real challenge. In order to respect the clinical constrains, a safety real-time controller has been designed.***

Keywords: medical robots, human interaction, safety

I. INTRODUCTION

An articulated and motorized mechanical structure, an HMI and instruments, electronic parts, and a software controller make up the sophisticated system known as a medical robot [1].

Medical robotics' key objective is to develop a partnership between man (the surgeon) and machine (the robot) that seeks to exploit the capabilities of both to do a task better than either can do alone [2].

Robotic technology can enhance surgeon perception, decision, and action on human patients in many ways, for instance, to vision systems, accurate actuators, and sensors. That is the reason why, over the last two decades, mechatronical devices are more and more present in operating rooms, especially in minimally invasive surgery (MIS) [3-7].

Medical robots must then function safely and with high reliability. Safety and reliability together with availability, confidentiality, integrity, and maintainability are the six attributes of the concept of dependability, [3].

Figure 1 shows the association between man and machine.

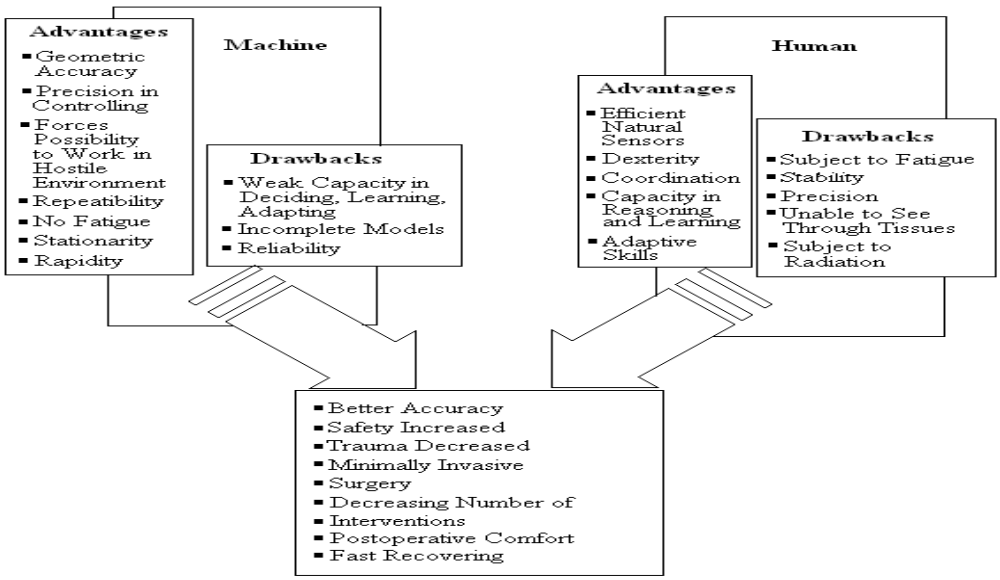


Figure 1. Association between man and machine

II. HUMAN FACTOR

A major characteristic of a medical system is to strongly interact with human environment (with possibly trained and/or especially not trained people who could have extremely unpredictable behaviour). A medical robot is usually a complex system including mechanical structure, human-machine interface (HMI), electronic components, and software controller. All these components are integrated to perform various tasks for daily medical applications. These applications are performed in a very cluttered environment (with a limited workspace, inside or outside the patient body) [5-6].

It is easily understandable that any failure may become very critical. Medical robots must then function safely and with high reliability. Safety and reliability together with availability, confidentiality, integrity, and maintainability are the six attributes of the concept of dependability, [3]. These attributes should become critical in the coming years as soon as computer-integrated surgery will become effective in the operating room. In this article, the focus is put on safety, today's challenging issue in medical robotics. Because medical systems are strongly interacting with their environment and are used in a completely different manner with respect to industrial robots, many safety requirements are needed. In the industry, robots are usually isolated from the workers who receive appropriate training to interact with them. This is very different in the operating room, where medical devices are generally in contact with the patient and the medical staff. Influence of human factor can be detailed as follows:

1) The work has to be done on a human being; thus, working conditions are not fixed but change with each patient (characteristics of soft tissues, position of the patient on the operating table, size of the body and accessibility of the organs, etc.). Consequently, the task and its execution are specific to a patient: "trial/error" or "doing again" movements are not allowed.
2) The robot is directly in contact with the pacient but also with the surgeon, the nurse, and the anaesthetist since it works in close cooperation with them. That is why a preoperative study is necessary in order to plan the intervention (perception and decision steps); the planning may be modified during the operation itself, according to the surgeon diagnostic, possible complications, or patient organism behaviour.
3) Since users are not "robotic specialists", a dedicated user-friendly HMI must be provided to the physician. It means that this interface is task oriented, allowing an easy manipulation of the system. More than that, the robot should be as transparent as possible, avoiding singularities, mechanical joint limits, etc….

III. CLINICAL CONSTRAINTS

Influence of clinical constraints specific to mechanical devices for medical purpose (not only in surgery) can be detailed as follows [8]:

a. Required functionalities are defined according to each kind of clinical operations; thus, new medical robots have often been designed for specific operations.

b. Every component of the system in contact with the sterile field must be sterilized: generally, the robot is covered by a sterile sleeve while the tool is separately sterilized by an autoclave procedure.

c. Environment is usually unstructured: all operating rooms are different and are cluttered with several other medical systems (radiology, anaesthesia, surgery, etc.). The position of the robot with respect to the patient varies between two operations on different patients but also during the same operation. Thus, its dimensions have to be reduced to comply with these constraints.

d. The robot has to be easily and quickly transportable in and out of the operating room. In the past decade, to meet these requirements, different design strategies have emerged especially based on technological solutions added to existing industrial robots.

Mechanical arms involved in medical robotic applications are classified in three classes depending on the level of autonomy and safety:

1) passive systems, that have no actuator and no autonomy (passive endoscopic devices, for instance)
2) active systems with actuated joints that perform planned operations on their own or in teleoperated mode
3) semi-active and synergistic systems for which power is cut-off during critical phases of the tasks and actuators are not directly used to guide the robot, but rather to help the surgeon to accurately position and handle his tools. Synergistic systems can be included in this class.

From a safety point of view, the motorless arms (passive and semi-active devices) are the safest. However, their possibilities are quite limited and motors are often necessary in most surgical operations. In this article we will focus on active systems.

Safety Rules

Medical robots do not have clear safety guidelines since there is no legal norm clearly enacted yet (excepted at the electrical level) [9].

In order to obtain the CE marking, the EN 46000 certification enacts the various criteria necessary to classify all the medical devices according to four classes:

- Class I: small degree of risk

- Class IIa: medium degree of risk
- Class IIb: high potential of risk
- Class III: very serious potential of risk.

By comparison, industrial robots belong to the last two categories (classes IIb and III), but the risks are usually avoided by protecting machine workspace from human intrusion. However, it is possible for an operator to enter this workspace under specific conditions without stopping the machine, and after disconnecting the protection devices, for instance, for maintenance purpose and under manual mode with limited speed [10-11].

In medical robotics, the key difference is that a human is always cooperating (surgeon) or interacting (patient) with the robot. Therefore, harsh constraints and specifications have to be considered in the design itself, especially for active medical devices.

To guarantee a high level of safety, a medical device such as a robot may be designed considering the main following principles:

1) the degree of redundancy in control and sensing
2) the possibility to design an intrinsically safe system (capacity to decrease the maximum level of risk by construction);
3) the trade-off between reliability and safety.

In the following sections, safety concepts based on these rules-redundancy and intrinsic safety-are described at the electromechanical, hardware, and software levels.

IV. ELECTROMECHANICAL AND ELECTRICAL SAFETY AND DESIGN

Time consuming and potentially hazardous initialization procedures may be avoided by using one absolute joint position sensor or a combination of two relative encoders.

In the latter case, one sensor is mounted on the motor output shaft (at the upstream of the reducer) for fine position sensing and the other is mounted on the joint axis for coarse sensing of the joint locations as presented in Figure 2: two resolvers may be used as in, one incremental encoder associated with an absolute encoder or associated with a potentiometer. Besides, this redundancy of sensors may be used for the arm control: for instance, information on the joint velocity can be deduced thanks to the coarse sensor.

Although electrical wiring is very specific to each robot (due to the actuator choice, the HMI complexity, the power requirement, etc.), some elementary rules should be followed to design the hardware controller.

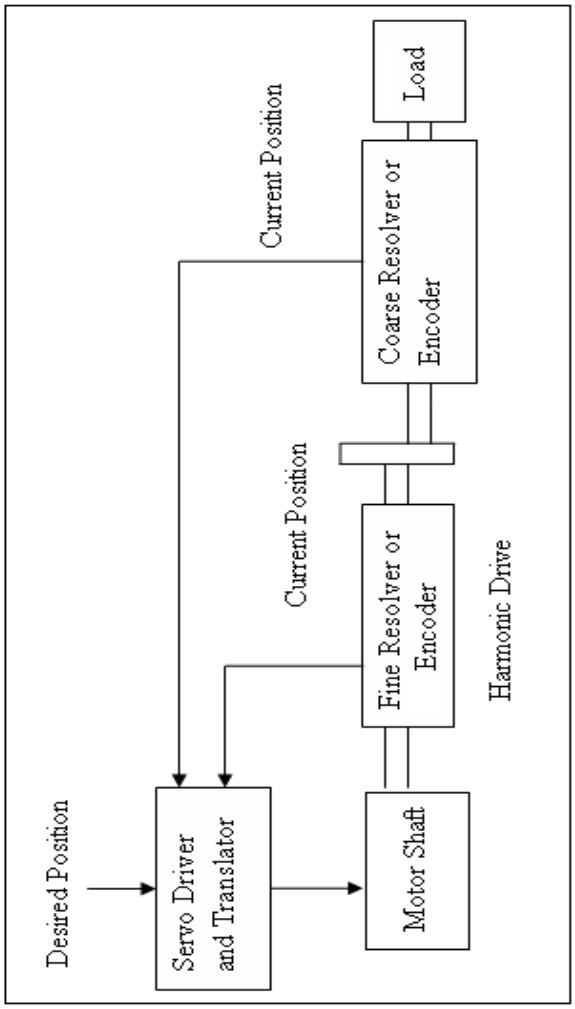


Figure 2. Combination of two resolvers.

The first absolutely mandatory component is the dead man switch (DMS). A DMS requires that the user exerts a continuous positive action to allow the motion of the arm; by releasing the switch (generally a pedal), the robot is stopped or decelerated. With industrial robots, emergency buttons with a good accesibility must be wired on the robot. Any punched action on this button switches actuator power off. Additional keys on the emergency buttons may be used to authorize only skilled staff to turn on the robot again. With these emergency buttons and a single on/off switch, power is only authorized when all status checking routines have been completed.

As for the mechanical redundancy, electrical components have to be duplicated in the hardware controller. According to the functionality, this redundancy is either parallel or serial. Generally, circuits such as watchdog boards or input/output (I/O) set up components are combined by a parallel assembly, where as relays, emergency switches, or buttons are serial wired.

V. REAL TIME CONTROLLER

Figure 3 shows the operating principle of the watchdog. A dedicated watchdog board allows checking the software process activity. A binary signal generated by the software at a constant frequency f is sent to the watchdog board; if this signal is stuck at a constant value over a fixed T time (with $T=1/f$), then the software is blocked, and the emergency circuit switches the power off.

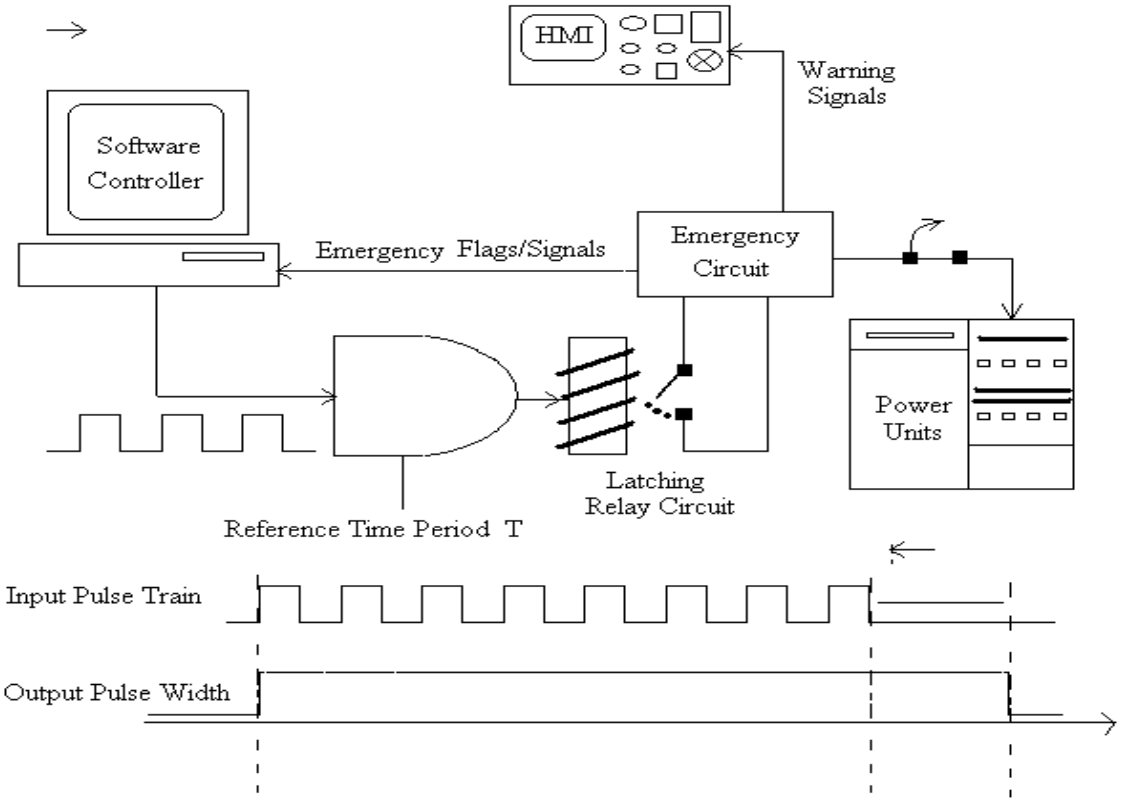


Figure 3. Operating principle of the watchdog.

The controller has been designed dedicated to specific tasks: security, Cartesian control, joint control, communication with peripheral units and sensors (one by units), HMI communication, etc. This methodology allows one to design the control software in an incremental manner, facilitating the validation phase. By tuning the process and variable priorities, an appropriate emergency procedure is switched on as soon as an error is detected.

Instead of using several processes, it may be interesting to duplicate the CPU. In this case again, each CPU is dedicated to one primitive function: for applications using tracking systems or tele-operated systems for instance, one CPU is dedicated to vision control, a second one to force control, and a last one to robot control.

Process activities are checked by a dedicated watchdog process: at each sampling period, time data are sent by the other processes. By comparing this data to the last one received, the watchdog can detect if a process is stuck in a blocked status.

Several additional hardware securities providing very good reliability and safety to the whole systems have been implemented. A DMS pedal authorizes any teaching or automatic motion.

Emergency buttons are available, wired on the control desk and on the controller front panel. Any action on one of these buttons immediately switches off the arm power. The arm is powered on only when a software initialization procedure is executed and when all the restart buttons are activated. On each robot, a watchdog board has been developed in order to manage the security from a software point of view. Due to the controller unit performance of the F/T sensor of Hippocrate, the sampling period of the system cannot be less than 10 [ms]. All electrical leads (including F/T sensor lead or laser telemeter) have been integrated inside the robot arms.

VI. CONCLUSIONS

This paper presented the influence of human factor and clinical constraints specific to robots for medical purpose. Designing medical robots for safe human interaction can be considered a real challenge because any failure may become very critical. Because any

failure may become very critical, medical robots must function safely and with high reliability, so that designing medical robots for safe human interaction can be considered a real challenge.

In order to respect the clinical constrains, a safety real-time controller has been designed. The controller has been designed dedicated to specific tasks: security, Cartesian control, joint control, communication with peripheral units and sensors (one by units), HMI communication, etc. This methodology allows one to design the control software in an incremental manner, facilitating the validation phase. By tuning the process and variable priorities, an appropriate emergency procedure is switched on as soon as an error is detected.

As a future work we try to perform a logical and time analysis of the software controller by Petri networks.

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