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The subjects of urban regeneration, health, environmental suitability and social sustainability are strongly linked to each other and they represent a great challenge that cities around the world had to face in the latest years. The experience made in the field of transition towards environmental and social sustainability has brought out quite clearly the importance of local dimension. In fact, every sustainable solution is acceptable, if it is effective also at local level. The present book reflects a first step in the development of a study carried out by an international research team, composed by Italian, Greek, Romanian and British experts, aimed at creating a soft methodology for designing very simple healthcare facilities within city districts, which will enhance the sustainable character of the choices and focus on the social rather than on the therapeutic actions run within these peculiar spaces. Within this essay, the various authors' contributions concern the subjects of health, environmental space, architectural design and performance, interior design and medical equipment as well as the perception of environment.

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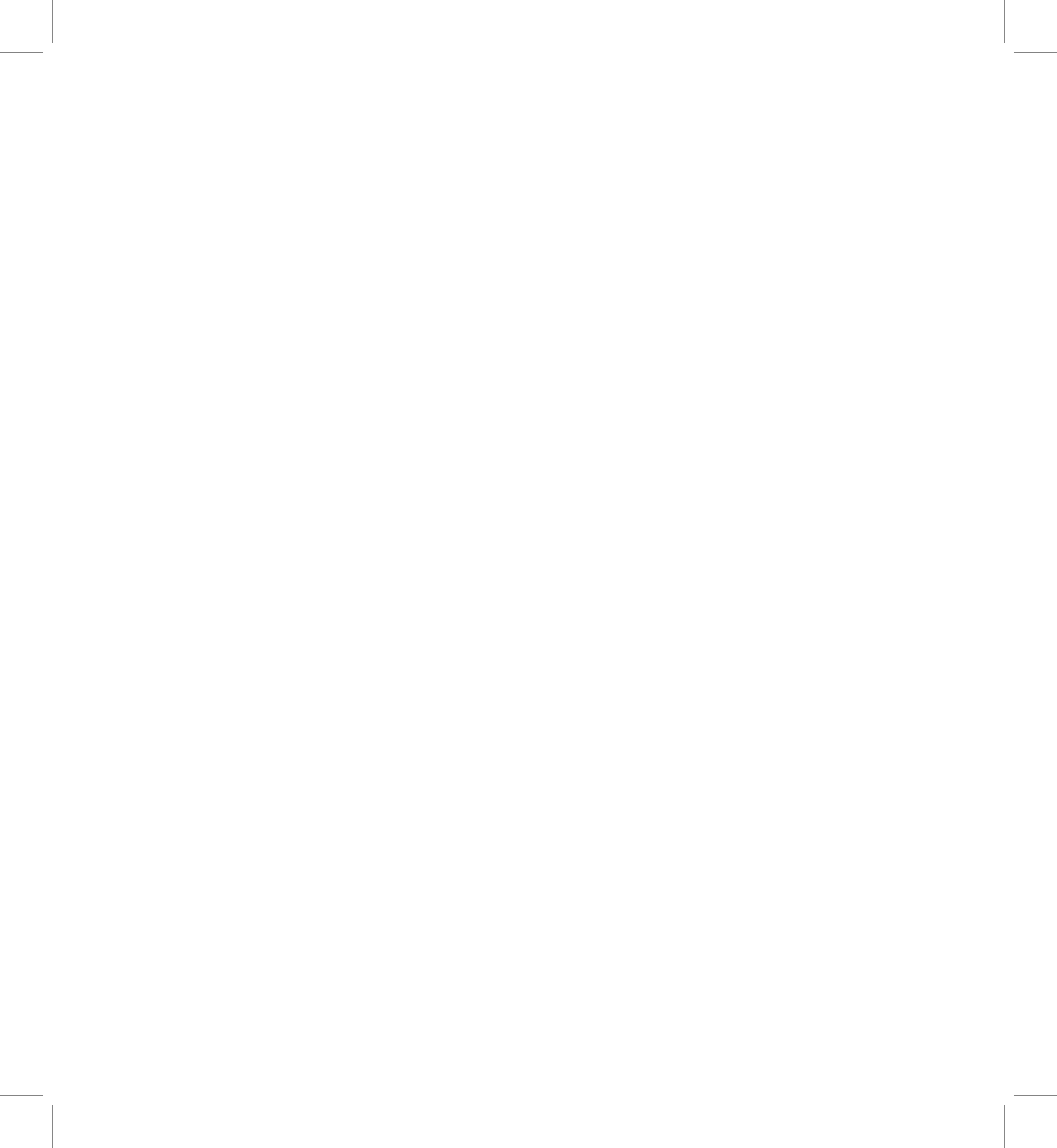
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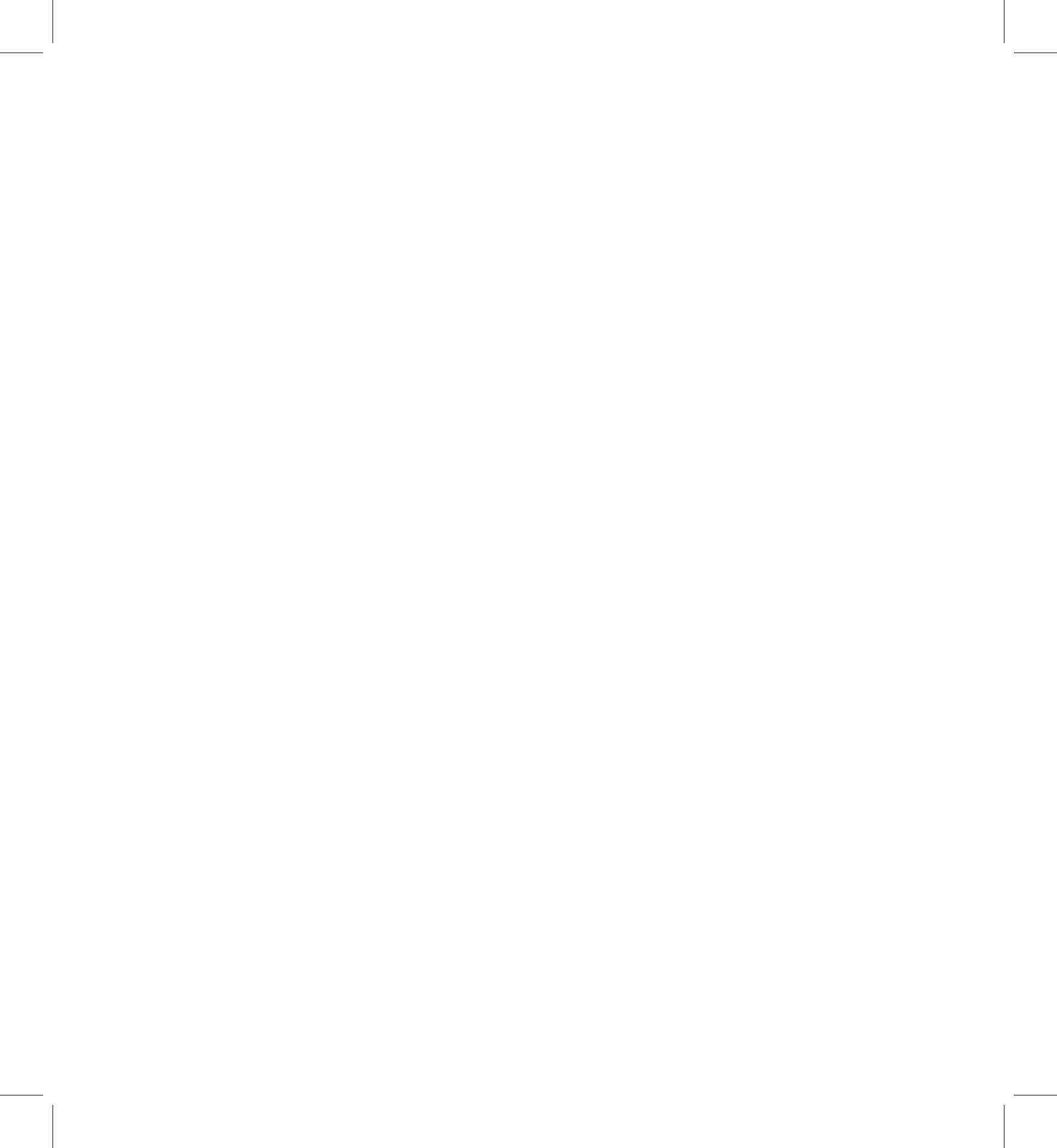
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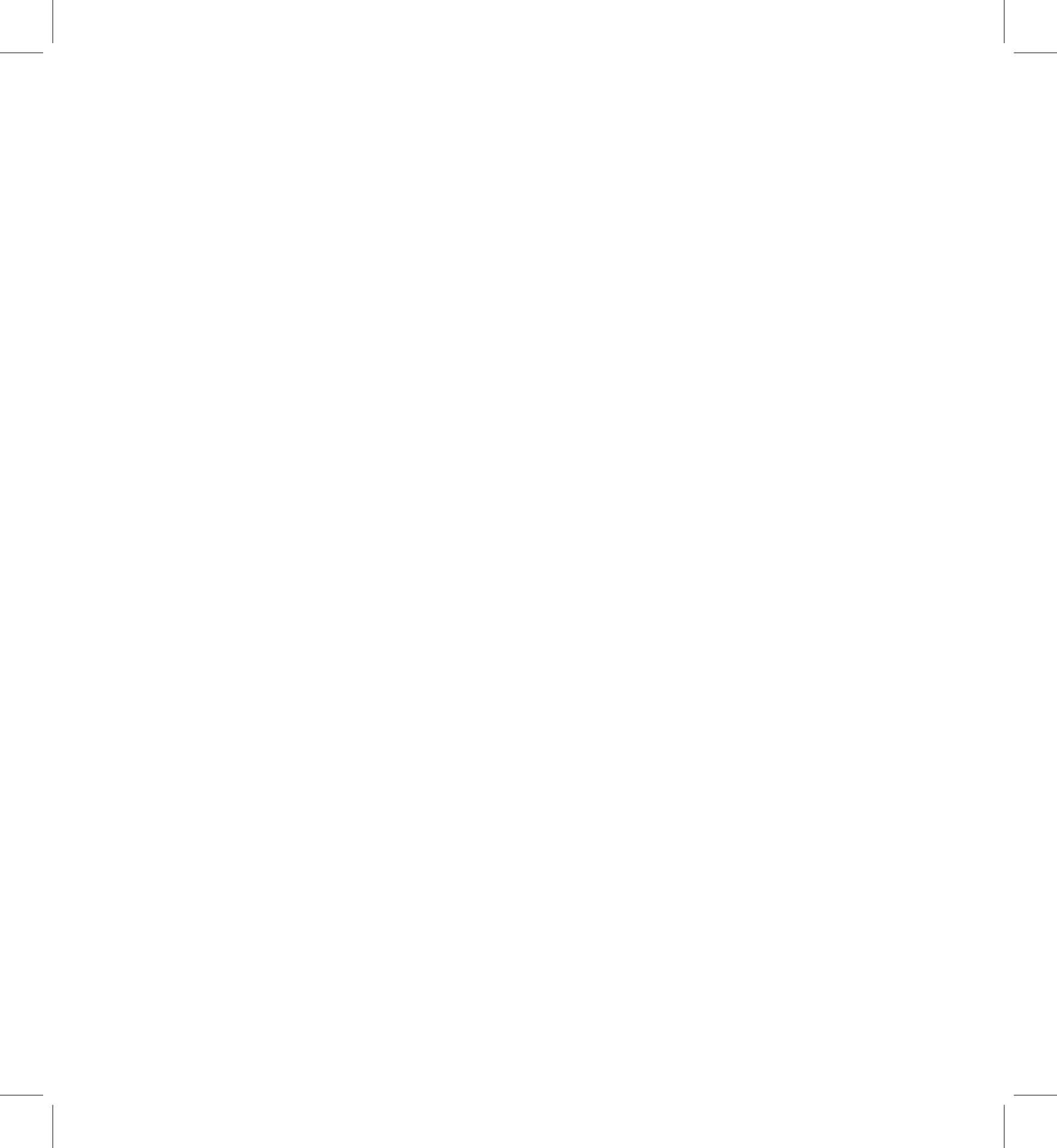
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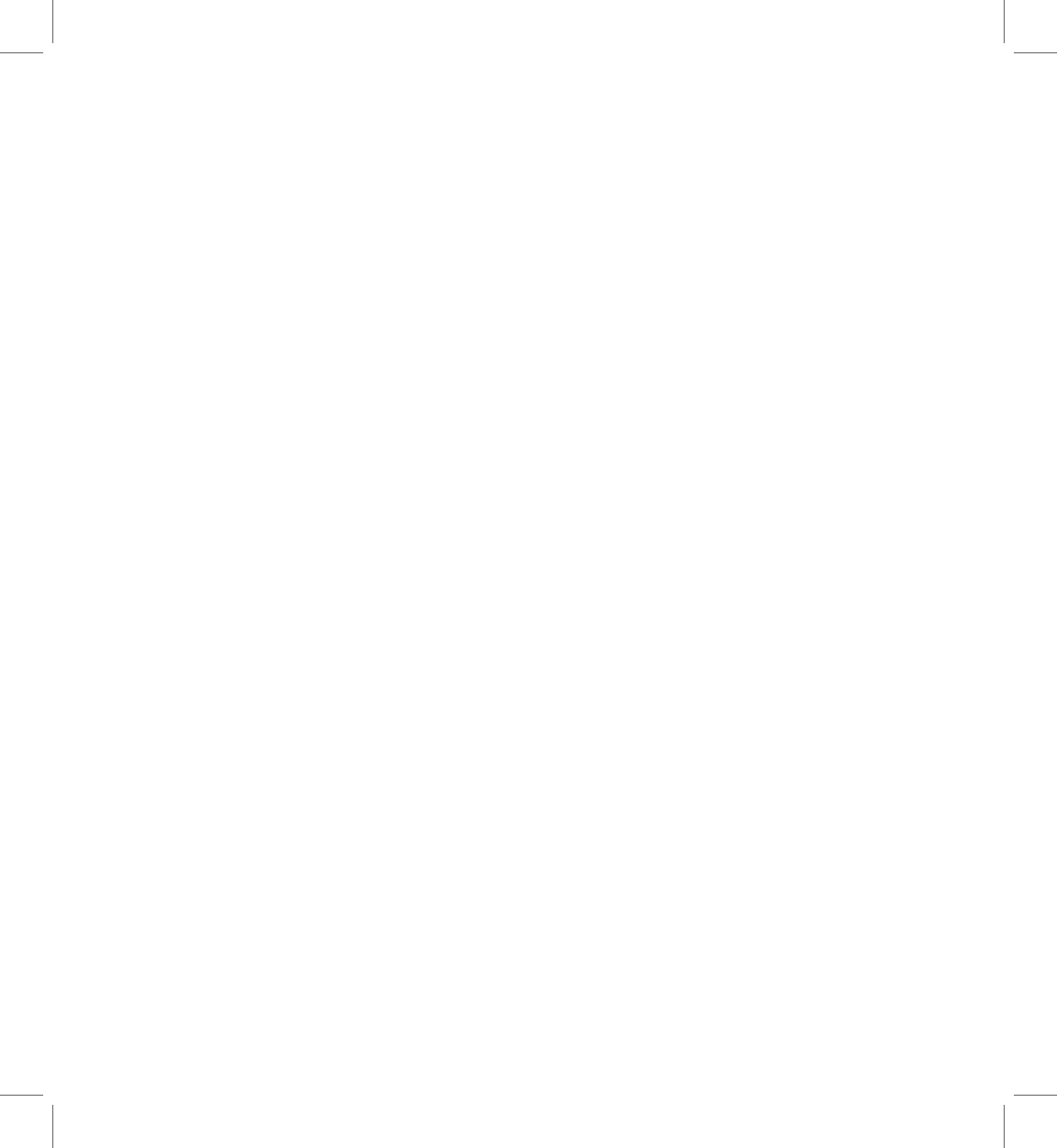
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Design for healthcare

*The role of
Ergonomics for
Design and
Human-Centred
Design approach*

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Abstract

Accident investigations suggest that the most of errors are due to deficiencies in user interface (UI) design.

User error occurs when a user does not interact with the system in the manner intended by the designer.

Given the importance of the current challenges launched by the healthcare sector, Design for Healthcare and specifically Design for medical technologies, assistive technology and medical devices, together with Ergonomics and Human-Centred design approach have the chance to face the status quo of health and care.

he ergonomic approach to the project, and

particularly, the usability evaluation and design methods of Human-Centred Design are appropriate for a field where “the phase of the product use” represents the main risk factor for users.

Special attention should be paid to an easier understanding of conditions of use and to reduce the risk factors in accordance with the potential difficulties and limitations of final users.

As a matter of fact, the project of a medical device implies the knowledge of the human factors, which focus on the interaction between the human and the system, as an instrument to minimize risks of use and ensure a safer and usable medical device.

Design for Healthcare

Design can be defined as “the ability of creative synthesis, based on the possibility to make innovative design solutions developing them into a product” (object of use, environment, service and/or hardware and software).

The role of design is “proactive intervention on the existing”. It is based on the ability to understand the complexity of the factors of innovation and changes that surround us, creating solutions suitable to users’ needs. In addition to this, Design can propose and suggest new lifestyles [1].

It is also necessary to consider that Design, as a field of research and action, works into a system composed by several disciplines; Healthcare Design is one of these.

In scientific literature, it is possible to identify 5 major areas where Design investigate various problems related to the healthcare sector.

These areas are the following:

- Design for Healthcare Architecture;
- Design for e-health;
- Design for Sustainable Healthcare;
- Design for Service Healthcare;
- Design for medical technologies, assistive technology and medical devices.

Today design for Healthcare, more specifically Design for medical technologies, assistive technology and medical devices, and consequently Ergonomics and Human-Centred Design represent an area of highly topical research.

The interest for this discipline increased alongside the rise of complexity of hospital care, technological innovation, usability of medical devices (MDs) and stakeholders and people’s expectations on the effectiveness of healthcare services [2-3-4-5-6].

Several researches show how the risk of accidents for patients caused by health management represent a social alarm. This led healthcare operators and managers to shed some light on the problem of safety, which needs accurate and direct answers [7-8].

Accident investigations suggest that the most of errors are due to deficiencies in user interface (UI) design [9-10]. Use error occurs when a user does not interact with the system in the manner intended by the designer. The importance of the current challenges launched by the healthcare sector allows Design for Healthcare to question the status quo of health and care through an increased use of Human-Centred Design methods (HCD) [11-12-13].

Such methods permit to increase the quality and usability of products, proposing new behaviors and life styles.

Well-designed devices, communication and services can reduce the stress and anxiety, can minimize errors and improve the user’s satisfaction, facilitating the patient’s health and recovery.

According with Ramachandran et. al [14] studies, the perceptual properties of artifacts, such as the symmetry of the shape,

orderliness, rhythm, contrast etc... are potential elements of positive and negative emotional responses.

For these reasons, design research is growing, concerning all patients' area: children, old people and temporary / long-term care patients.

The role of Ergonomics for Design and Human-Centred Design approach

The ergonomics is a theoretical and application research sector. It is initially based on the study of human-machine system addressed to the interdisciplinary knowledge of human factors, with a focus on the limits, abilities and needs of man at work.

Subsequently, the ergonomics extended its areas of interest towards sectors of human activities, to involve the study of needs and capabilities of the human beings in their life and work activities [15].

International Ergonomics Association (IEA) defines Ergonomics or Human Factors as: “the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance” [16].

In this context, the term “system” refers to the physical, cognitive and organizational artifacts people interact with. The system can be a technologic item, a software or a

product, such as medical device, even a person, an organization or a physical environment.

The aims of Ergonomics are usability and security of systems. The human being plays the role of user (operator, user, buyer and customer of facilities, products, environments and services) and represents an integral part of the system itself.

Standards recognise the usability of medical devices as a basic factor to ensure patients' safety and to protect well-being and daily life quality. The usability affects the reduction of family assistance care and the optimization of services offered by health facilities.

The Annex I to D.lgs 37/2010, which will be replaced in 2020 by Regulation (EU) 2017/2017, establishes the relationship among requirements of safety and “ergonomics characteristics of devices”, including the evaluations of such requirements, “the environment in which the products is used” and the consideration “of the technical knowledge, experience, education and training, and where applicable the medical and physical conditions of intended users” [17].

The international standard ISO 9241-210:2010 [18] defines Human-Centred Design as an approach addressed to design and development of systems aimed to ensure interactive systems more useable by applying human factors and the usability knowledge and techniques.

The same standard argues that using a human-centred approach to design and development has substantial economic and social benefits for users, employers and suppliers. Highly usable systems and products tend to be more successful both technically and commercially.

Systems designed using human-centred methods improve quality, such as, by:

- increasing the productivity of users and the operational efficiency of organizations;
- being easier to understand and use, thus reducing training and support costs;
- increasing usability for people with a wider range of capabilities and thus increasing accessibility;
- improving user experience;
- reducing discomfort and stress;
- providing a competitive advantage, for example by improving brand image;
- contributing towards sustainability objectives.

The key principles of Human-Centred Design as follows [18-19] (see fig01):

- the design is based upon an explicit understanding of users, tasks and environments;
- users are involved throughout design and development;
- the design is driven and refined by user-centred evaluation;
- the process is iterative;
- the design addresses the whole user experience;
- the design team includes multidisciplinary skills and perspectives.

Some authors claim that each dollar spent on usability generates a return from 2 to 100 dollars [20-21].

It is therefore necessary to focus on the human factors and the application of HCD techniques; their correct implementation can improve the system remarkably.

The ergonomic approach to the project, and specifically the usability evaluation and design methods of Human-Centred Design are appropriate in a field where the “use phase of the product” represents the main risk factor for users. Special attention should be paid to an easier understanding of conditions of use and to reduce the risk factors in accordance with the potential difficulties and limitations of final users.

The methodologic approach of Ergonomics, in its double meanings of Human Factors and Human-Centred Design, is based on the synthetic capacity of Design, and specifically on the ability to translate the opportunities offered by technology and the complexity of needs into innovative design solutions.

Design can be considered as a strategic factor even in a highly specific sector such as the one of medical devices. Thanks to its capacity to respond to every changing need and expectation of the users, Design can improve the products quality and their usability.

The aim of Design is to create innovation, meant as radical or incremental improvement of a product, and creation of new meaning and languages.

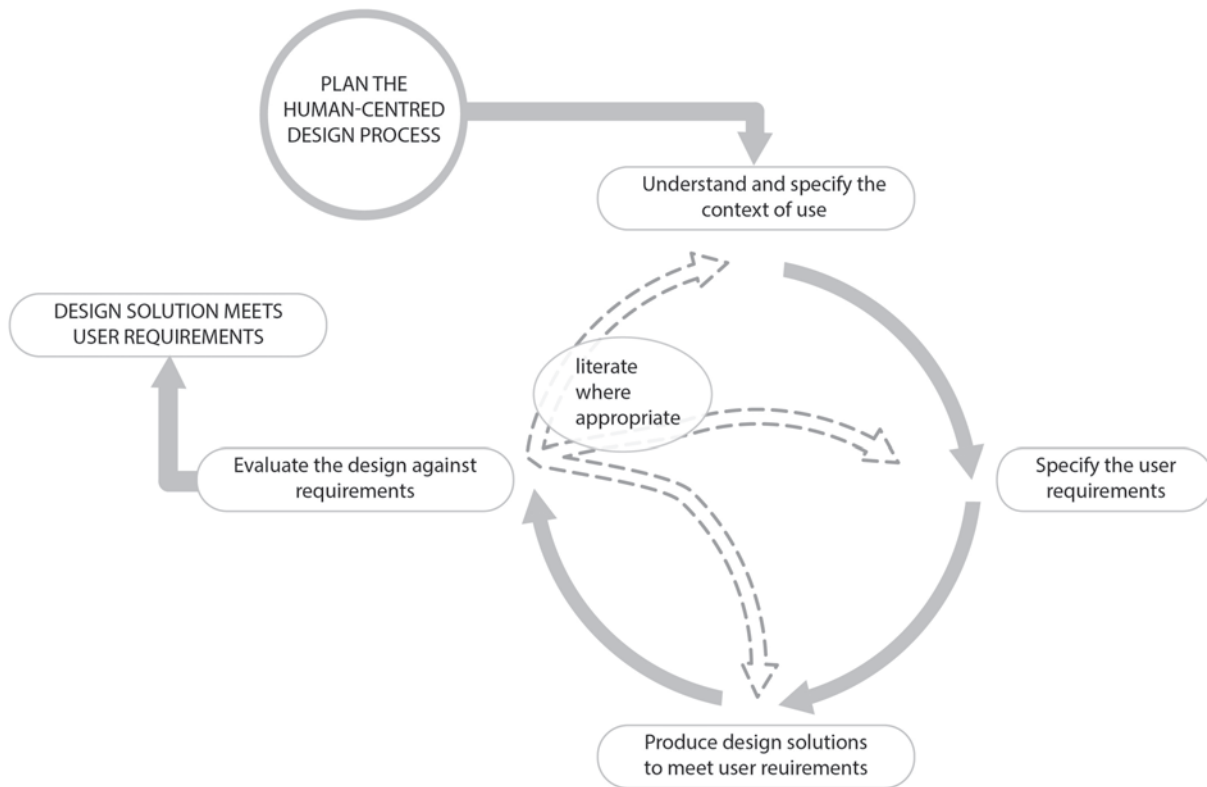


fig01 - Interdependence of Human-Centred Design activities

The potential and advantages offered by adopting the HCD approach in the design of Healthcare devices and services is demonstrated by products such as OcuCheck and Computed Axial Tomography. OcuCheck is an ocular medical device produced by InnSight Technology Inc. company. Its design is based on the application of a few HCD methodologies (Task Analysis, observation and Field Observation) with the aim to satisfy users' needs, in particular the ophthalmologist and patient's needs (see fig02).



fig02 - Ocu Check, Santobono Pausilipon children's hospital, Naples.

Medical devices such as the CAT (Computed Axial Tomography) can be user-friendly designed also. The new model of CAT by General Electric Healthcare is child-friendly because designed to look like a pirate ship. In this case, the medical staff transforms the medical experience in a story rather than tell kids what to do. Children are less scared and more willing to follow instructions and a large percentage of children do not need anesthetics before using the device, saving time, money and improving the effectiveness of the medical procedure (see fig03).

Cases study.

The ergonomics evaluation of anesthesia workstation

The usability of medical devices is defined by international standard ISO 9241-210:2010 [18] as: “extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use”.

It represents an essential requirement to ensure users’ safety. Unfortunately, only a few of medical devices are exemplary.



fig03 - Computed Axial Tomography, Santobono Pausilipon children's hospital, Naples.

This is due to the fact that a lot of errors in healthcare are caused by the difficulty of using the device; sometimes the device simply does not meet the users' mental models. Despite manufactures of medical devices claim that Human Factors have a high priority in their projects, few of these are flawless products from the perspective of design and human-machine interface.

According with many scientific studies concerning incidents in healthcare, especially in the anesthesia field, a usability test was conducted on an anesthesia workstation. Ergonomics and design methodologies were used to conduct a usability test with device. The evaluation was useful to determine the product ability to satisfy the operators' needs and if it could cause use errors with effects on the operator and the patient.

The study was conducted into the surgery of two Tuscan hospitals with the involvement of specific categories of users.

The test involved 5 anesthetists and 6 nurses with a varying background and age. It was performed on the base of the following methods:

- Interview;
- Hierarchical task analysis;
- User Observation;
- Questionnaire;
- Gap Analysis.

In order to gain more information about usability level of anesthesia workstation, two groups of different users were selected:

- Group 1, which use anesthesia workstation daily - expert users;
- Group 2, which has not used the anesthesia workstation yet - inexperienced users.

Preliminary interviews were conducted with the medical-health staff to define the critical issues that operators can experiment during anesthesia workstation interaction, in order to apply significant tasks to an ample range of habitual activities.

Concerning the tasks that operators perform daily during anesthesia workstation interaction, 3 tasks for anesthetists and 3 tasks for nurses were selected.

Specifically, tasks for human-machine interaction and tasks for human-interface interaction were selected.

As for the doctors, the following tasks were identified (see fig04):

- Task 1- Alarms setup (CO2 and Apnea);
- Task 2 - System setup (Waveform and layout display);
- Task 3 - handling anesthesia workstation.



fig04 - System and alarm setup.

While as for nurses, the following tasks were selected (see fig05):

- Task 1 - removing and placement of breathing system;
- Task 2 - removing and placement of absorbent canister;
- Task 3 - handling anesthesia workstation.

These differences are helpful to relate the current usability of device, regarding to the different degrees of experience of each operator. After the observation and evaluation phase the Gap Analysis was settled. This allowed to identify the usability level of anesthesia workstation from the doctors' and nurses' point of view, and to conceive proposals for improvement.

As described in the user manual, even in case of a preliminary simulation, the precise timing for each task were estimated. For this specific study, the time is a key variable for the usability of the medical device. Therefore, the greater the time spent by the user to accomplish the task, the lower the usability of medical device and vice versa [23]. To evaluate the usability of anesthesia workstation the Nielsen's success rate metric was used. As defined by Nielsen himself, it is the percentage of the activities that users have successfully completed [24].

Success rate were determined as follows:

- S, Success, value 1.
The user completed the task in time;
- P, Partial Success, value 1/2.
The user spent more time than expected to complete the task;
- F, Failure, value 0.

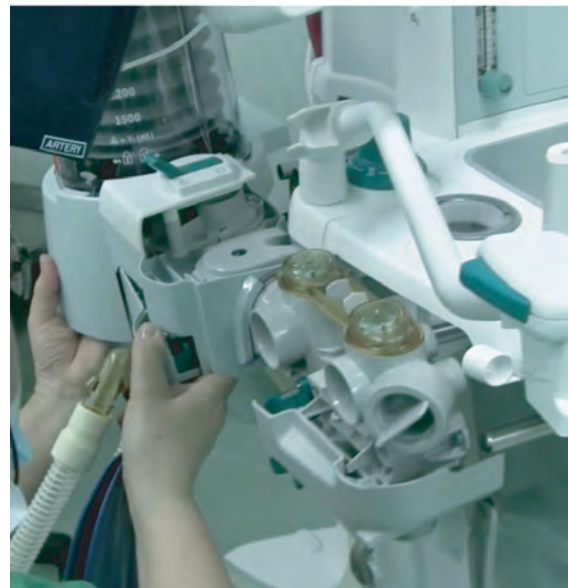


fig05 - Removing and placement of absorbent canister (at the top) and removing and placement of breathing system (below).

The user did not complete the task in time. To identify the success rate, the following formula was used:

$$\frac{\sum S + \sum P/2 + \sum F}{\sum \text{Tasks}} = \% \text{ success rate}$$

As for the doctors the success rate is 52% while as for nurses the success rate is 75%. Once the usability levels have been identified, the current situation of device (how operator uses the anesthesia workstation) and the desired outcome characteristics (what characteristics the anesthesia workstation should possess) were subsequently analyzed. Comparing the two lists, the following Gap were identified (see tab 01).

Conclusions

In conclusion, the methodologies of Ergonomics and HCD approach represent a strategic factor, even in a highly specific sector such as the one of medical devices. They can improve the quality of products and their usability, permitting to identify new future scenarios and solutions that meet humans' needs and expectations.

Therefore, it is fundamental that the project of medical devices implies the knowledge of the human factors, which focus on the interaction between the human being and the system, as an element to minimize the risks of use and to ensure a safer and usable medical device.

TASK	CURRENT SITUATION	DESIRED OUTCOME	THE GAP
Alarms setup (CO2) and Apnea)	The alarm setting is not very intuitive	The operators should have easier access to the alarms setup	The system and hierarchy of information do not help the operators during performance of the tasks
System setup (Waveform and layout display)	The system setting is not very intuitive	The operators should have easier access to the system setup	The system and hierarchy of information do not help some operators during performance of the tasks
Removing and placement of breathing system	The breathing system was removed with difficulty	1. The anesthesia workstation should facilitate the operator during performance of the task 2. The device should have appropriate gripping points to facilitate the operation	The breathing system button does not provide adequate information about its use
Removing and placement of absorbent canister	The absorbent canister was removed and was placed with difficulty by some operators	The anesthesia workstation should facilitate operator during performance of the task	The hooking and release system does not help some operator to complete the task
Handling anesthesia workstation	1. Some operators exert considerable force to handling the anesthesia workstations 2. Some operators do not use the appropriate handles	The operators should move the anesthesia workstation more easily and exercising less strength	1. Weight of anesthesia workstation 2. Side handles

tab01 - Gap analysis

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