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Designing Cognitive Ergonomics Features of Medical Devices. Aspects of Cognitive Interaction

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Abstract: This research studies three areas of interest: Healthcare sector, the discipline of Cognitive Ergonomics and Design for Health with the aim of developing the guidelines for designing a correct physical and cognitive interaction with Medical Devices. Therefore, the analysis of Cognitive Ergonomics features was done that has been so far finalized with the first systematization of these features, that evidenced some issues and opportunities for design intervention. In particular, the features have been divided into two groups: rational and emotional aspects of cognitive interaction, where the latter introduces more questions than answers, however, the first 'layer' of design questions is proposed as the base for the future guidelines. This Ph.D. research is being conducted in collaboration with an Italian manufacturer of devices for neonatal care that provides a case-study for further testing of the research proposals and results.

Keywords: Healthcare, Cognitive Ergonomics, Rational, Emotional, Design Guidelines

1. Introduction

This paper aims at sharing the process and first results of a Ph.D. research on the theme: Designing Cognitive Ergonomics Features of Medical Devices: from user experience to cognitive interaction. In particular, the final objective is to develop tools/guidelines for designing a correct physical and cognitive interaction with the Medical Devices. One of the concerns that appeared during the research was the importance of patients' emotional state when they are reading the information regarding their health condition, and in particular, when the patient is in a hospital and has to react to the signals of the medical devices that are designed for medics and not for non-professional users.
The research is held in the field of Product Design at Sapienza University of Rome and in collaboration with an Italian company, a manufacturer of neonatal healthcare systems, and it is divided into three areas of interest: «Healthcare sector», «Cognitive Ergonomics», «Medical Design». The study has started both from theoretical research and a practical request from the Company. The Company is working on a new line of products and in particular is interested to rethink and redesign the interaction with a neonatal nasal

ventilator[1]. The product is a computer with a monitor that regulates the temperature, humidity and the speed of the air that is, by passing through the tubes, enables baby's breath. The fact that it is the computer that regulates all the process means that a person has to interact with the product through software, and thus to read and evaluate big amounts of visual information. That makes the interaction with the product mostly cognitive, rather than physical. Therefore, the task to rethink the interaction with 'Giulia' requires such design tools that would refer to human's Cognition and Psychology. The scientific discipline that works with these aspects and that can provide useful methods for analyzing cognitive interaction process is Cognitive Ergonomics. According to the definition provided by IEA (International Ergonomics Association)[2]: "Cognitive Ergonomics is concerned with mental processes, such as perception, memory, reasoning, and motor response, as they affect interactions among humans and other elements of a system. The relevant topics include mental workload, decision-making, skilled performance, human-computer interaction, human reliability, work stress, and training as these may relate to human-system design." Thereby the research has focused on analyzing and systemizing features of Cognitive Ergonomics in order to improve the interaction between a person (in this case both doctor/nurse and patient) and other elements of the system (medical device(s), working environment) to then develop tools/guidelines for Designing Medical Devices that would include cognitive aspects of interaction into them. By studying this, the research has come to an observation that there are some features of the cognitive interaction that are addressed more, and there are some that are addressed less, which lead to the need of analysis of the aspects of these features in order to find the necessities and possibilities to intervene as designers. In particular, Cognitive Ergonomics in the Medical field is principally occupied with the problematics of Decision Making and Errors done under a certain Mental Workload by a medic professional, while the emotional impact on the patient is generally not taken into consideration (see journals like Biomedical Informatics[3], Medical Informatics[4], etc.). It is also quite typical that traditionally the patient is not included in the interactive process with the medical devices. Design discipline instead pays more attention to the user experience and possesses some methods and tools that include the emotional state as one of its objectives (Norman, D. A., 2004). Thus, the next paragraph will be dedicated to an overview of the Healthcare sector, to the state-of-the-art in Cognitive Ergonomics and to the role of Design as an innovation tool for the Healthcare sector and as a method to research. In the following paragraph, the systematization of the Cognitive Ergonomics features into two groups of aspects, rational and emotional, will be proposed. Eventually, the first proposal of the future guidelines will be demonstrated. The research is now at the phase of preparing the tests of the theoretical findings and is now setting the tools for designing a correct cognitive interaction with the medical devices.

[1] www.ginevri.com/Prodotti.aspx?id=11&l=en-US

[2] www.iea.cc/whats/index.html

[3] Shortliffe, E.H. (ed.), *Journal of Biomedical Informatics*, ISSN: 1532-0464

[4] De Fatima Marin, H. (ed.), *International Journal of Medical Informatics*, ISSN: 1386-5056

2. Background and Context

2.1 Healthcare sector: reasons to intervene

Healthcare system typically depends on social, cultural and political background, on economics and technologies, and therefore the scenario varies depending on the context of action, which means that some evidence and tendencies that are applicable to one scenario may be not applicable to another. It is anyway useful to mention some core issues and general tendencies that distinguish the contemporary state of a [western] healthcare system, as well as its technological possibilities and the opportunities that they open to the users:

- in 2005 the Wired magazine has identified healthcare sector as the most dysfunctional and at the same time the most adaptable to the disruptive innovation, while it needs at least 30 years in order to standardize the scientific findings in the sector (Varkey, P. et al, 2008);
- parallelly to that, the e-Health technologies are developing rapidly and are bringing empowerment to the user, who is becoming more and more informed, by providing access and helping the physician, the sick person and the healthy one to manage his/her health status at the different phases of care. People have a growing focus on their health, and this creates opportunities for the development of prevention strategies, rather than delivering acute care, facilitated by the spread of technology 4.0 in all healthcare sectors;
- from the conceptual point of view, it is possible to affirm that the field is characterized by the significant shift in the concept of health, which is moving from the idea of «physical well-being» and «absence of disease» (World Health Organization, 1948[5]) towards the «ability to adapt and self-manage in front of social, emotional and physical challenges» (Huber et al., 2011), and thus it is absorbing larger concepts and more disciplines within itself. Health can be considered not as a simple absence of biological agents that cause illness, but as a result of a harmonious physical and psychological balance of the individual, dynamically integrated into its natural and social environment (Seppilli, A., 1996).

Seeing that, it is possible to say that the Healthcare sector is now in the period of transformation and is close to a revolutionary change due to the fact that it has gathered in itself both scientific and technological achievements and a conceptual change. The empowerment of the user gives centrality to the healthcare sector and wellbeing in people's life since it is now becoming more and more possible to act independently and control and monitor one's health status. The restrictions of the standardization process due to various risks (e.g. of heavy health conditions, big economic investments, bureaucratic reasons) slow down the process of change, but despite that and probably because of that the Healthcare sector requires more innovative solutions that would take into a consideration all the aspects including the growing responsibility of the 'empowered' patient as well as all the consequences of this responsibility (e.g. psychological, legal). Thus, the system should allow a higher level of adaptation in the face of these changes, and it is here where can be seen an opportunity and a reason to intervene as designers.

[5] www.who.int/

2.2 Cognitive Ergonomics Features

Bartlet in 1962 has deducted the reduction of physical workload and the increase of mental workload, together with the emphasis on the activities connected with decision-making, and in fact, nowadays, there are many pieces of research in the field of medical informatics that are specialized and focused on the issues related to the decision-making process. Cognitive Ergonomics as a discipline studies mental processes involved in the interaction between a person and a tool (like decision-making) and seeks to split every aspect of this interaction in order to improve each of them and thus make the interaction more effective and efficient. The specificity of the ergonomic approach consists, in fact, in the ability to evaluate the multiplicity of variables that define the user-product interaction. Its main objectives are "the adaptation of labor to man" (Murrell, H., 1965) and "compatibility between the skills of the operators and the activities required by their duties "(Sanders&McCormick, 1998).

The relationship between user and product is based on the physicality of our contact with the environment and the object, on the possibility of seeing, touching, manipulating forms and materials (Tosi, F., 2005, p. 38). Classical Ergonomics studies physical interaction, and its research areas include anthropometry, biomechanics, occupational ergonomics, the study of sensory processes. Cognitive Ergonomics adds mental processes as well as some other components of the User Needs such as social, cultural, emotional values. Initially, Ergonomics studied only objective aspects of the interaction, like functionality, usability, effectiveness, efficiency, etc. Now it shifts towards subjective, emotional components. It is observed that we are leading from the world of necessity towards that of desire (Di Nocera F., 2011, Tosi, F., 2005). This way the interaction between the user and the object can be seen more like a relationship, that needs to be established (Jordan P.W., 2002). But it doesn't mean that the functionality and necessity are not important.

Since Ergonomics has entered into Product Design, the point of reference is no longer an average worker, but people with all their differences. One of the new fields of intervention of ergonomics is products and equipment for healthcare and assistance in which ergonomics is configured as an instrument of innovation able to intervene in all phases of the training and development processes. Ergonomic intervention is required as an evaluation tool placed mainly in the phases of verification of prototypes or physical products, as an external contribution. It would be though also efficient to insert Ergonomic Analysis directly into the Design Process in order to optimize and adjust product’s features before it has been produced or to have easy access to the elements that would allow making changes at each phase of the design process.

As it was mentioned before, there are some features of the interaction between user and object related to Cognitive Ergonomics that are studied more, and there are some that are studied less. The literature review has evidenced the following aspects of interaction that all together represent its cognitive and technological complexity: Operator's Functional State and mental workload, decision-making, errors, the functionality of the object, interaction with the object and its technologies, perception, subjectivity (see Figure 1).

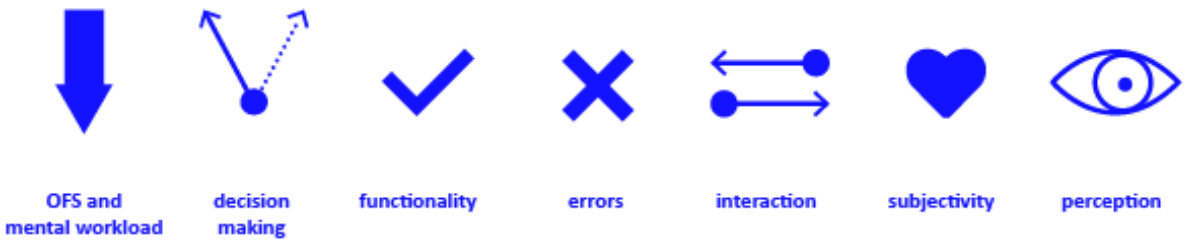

Figure 1. Cognitive Ergonomics Features

In the medical field, the crucial aspects are the first five ones, and especially the first three ones as they are directly connected with cognitive processes that lead to actions of the medical professional(s) involved in the process, and thus influencing health conditions of the patient. In the medical field 'perception' and 'subjectivity' are often not subjected to ergonomic analysis as it is believed that they are not related directly to the actions of the physician. Also, from a conceptual point of view it is not exactly correct to separate perception and action as they are not seen anymore as different actions where one follows the other, but, thanks to the theory of Affordance proposed by J. J. Gibson (1966), have been united into a single, inseparable, interdependent process. And if perception affects following actions, then it seems to become an important aspect of interaction to consider as a part of the design process.

Seeing definitions and utility of Cognitive Ergonomics (CE) discipline, it becomes possible to observe some similarities to the Design process, as both of them focus on the User Needs and provide tools for projecting and planning. CE has even absorbed some Design approaches, such as Participatory Design or User-Centered Design that allows including the final user into the analytical and design process (Di Nocera F., 2011). But what Cognitive Ergonomics might be missing? CE provides analytical tools while Design includes tools of making, visualizing, and planning. In the following section, the role of Design will be framed regarding the Healthcare sector and as a method to proceed with the research.

2.3 The role of design in healthcare system

Literature Review and Design Thinking are being used as a method in this research in order to analyze the context and to understand the coming-out issues that might be important for the field and thus to set the possible further actions. In this paragraph, the role of Design in Healthcare system will be defined as well as the method that is being used in order to approach the interdisciplinarity of the research.

> There are many drivers for health service reform; a rise of long term conditions, an aging population, a health service that has evolved to deliver acute care rather than primary care, reduced funding and rising expectations from an increasingly informed population. These are some of the key challenges to society today, and ones that require a new way of thinking, a radical step change, and innovative approaches in the ways we deliver care. (Chamberlain P. et al., 2015, p.7)

It is considered that the issues around health are by definition 'wicked problems', to which there is no single correct response, and that is where the strength of Design is considered

to lie. Design as a mindset, as a method and as an approach to the unknown, «wicked» scenarios offers its tools for the research and in particular allows to enter into other disciplines being the outsider, and thus looking into it with the new eyes, free from preconceptions. Design has also an increasing recognition as an important factor for the design of innovative products as it has the role of «coordination, integration, and articulation of all the factors, which, in one way or another, participate in a formative process of the product», according to the classic definition by Maldonado (1976). Currently, in the Healthcare sector, just as it is in many other fields, the Design is seen as a synonymous of innovation (Chamberlain et al., 2015). In particular, different fields of Design provide their specific contribution to the healthcare system, for example: Service Design is working on the improvements in the delivery of services and products both inside and outside of the healthcare system; Behavior Design based on psychological studies, influences human behavior; Interaction Design optimizes the interconnections between people, products, services and ambiance; and User-Centered Design has brought design towards Co-Design, Participatory Design and thus has created a more close relationship between the designer and all the stakeholders involved (Tsekvelets&Cooper, 2017). In addition to that, Design Thinking as an integrated approach of thinking is now often applied to diverse fields, and to the healthcare sector as well. According to the Stanford d.school method[6], it provides the following 5 steps to approach any design problem, each of them accompanied by corresponding tools:

1. step 1. empathize (tools example: interview, desk research, field research),
2. step 2. define (e.g. mindmap),
3. step 3. ideate (e.g. brainstorming),
4. step 4. test (prototyping, mock-ups, etc.),
5. step 5. iterate.

Empathizing plays the key role in understanding the user's needs along his path of interaction. In this research, the 5 steps of Stanford's methodology is used in order to enter and understand the Healthcare scenario, the interaction processes and the discipline of Cognitive Ergonomics and eventually to design the guidelines for designing cognitive interaction with Medical Devices and thus to provide innovative insights for the Company. In particular, the author is interested in understanding the impact of both the overall look of the Product (nasal ventilator), an impression it leaves on the user and the information it communicates to him/her. Benchmarking analysis has evidenced some contradictive challenges of usability design such as an information need and overload, patient overload and limited availability of healthcare professionals. These factors confirm the need for accurate analysis of the interaction process in order to equilibrate the unbalanced aspects. Since Design Thinking is an iterative process, the present research is now at the step 3 refined through the steps 1-2-4. In the following paragraphs, the first results of steps 1-2-3 will be explained in order to then conclude with a proposal of the future guidelines.

3. Aspects of Cognitive Interaction

The final objective of the research is to develop a tool and/or guidelines for designing a correct interaction, both physical and cognitive, with Medical Devices. As it was shown in previous paragraphs, the literature review has evidenced some features of cognitive ergonomics, that are: Operator's Functional State and mental workload, decision-making, errors, the functionality of the object, interaction with the object and its technologies, perception, and subjectivity. Altogether they may be divided into rational and emotional

[6]dschool.stanford.edu/

aspects. In this paragraph, a brief summary of the issues around these aspects will be demonstrated in order to make the first proposal of their systematization as it is useful for the design process and for building guidelines.

3.1 Rational aspects

What is rational? According to a definition of the Italian Encyclopedia Treccani[7], the word rational means «*che procede dalla ragione, che è condotto secondo il rigore logico, di metodo e scientifico, che è proprio della ragione*» (which proceeds from reason, which is conducted according to the logical rigor of method and science, which is proper to reason[8]). According to that, the following Cognitive Ergonomics features, such as Operator's Functional State and mental workload, decision-making, errors, the functionality of the object, interaction with the object and its technologies, were grouped as Rational aspects of cognitive interaction, as they address logical sequences of actions. However, as it will be shown further, the rational aspects are not always purely rational, but 'polluted' by emotions.

Operator's Functional State and Mental Workload:

In order to complete any task, an individual needs resources [mental]. It is considered that the optimal condition for performing a required task is when an individual possesses more resources than needed and when the Mental Workload is lower (see Figure 2). Thus, the objective of the researchers is to predict the phases of work in which operators could be overloaded (F. Di Nocera, 2011) in order to design such sequence of tasks that would require minimum possible resources.

Figure 2. The optimal task position in respect to mental workload and resources

Decision-making:

Decision-making is a very important moment in healthcare activities. Starting from XVII century, various theories were developed, among which the Expected Utility theory (Neuman & Morgenstern, 1947) that proved to be effective in market scenarios, that were based on finding the most adequate criterion that would allow predicting and calculating the decision that a person would adopt in a certain situation. While from Kahneman and Tversky (1979) and further, the researchers have focused on the real situation in order to

[7] Il Vocabolatio Treccani, 2018, Istituto della Enciclopedia Italiana fondata da Giovanni Treccani, ISBN 978-88-12-00707-3

[8] translation by the author

understand how people make decisions in real life, which involve heuristic instants and emotions. The latter gives us the awareness of the presence of hidden psychological processes that is difficult to 'calculate' but is impossible to dismiss.

Considering the hospital environment, there are several observations regarding Decision-Making scenario. In particular, the fact that it is spatially distributed and involves numerous actors, many of which never meet face-to-face but each of the adds their own contribution and report, which is then read and interpreted by other actors. “As a consequence, health work is both, strongly interactive, experience-based and immediate and at the same time requiring constant coordination and alignment with the work of others across departmental and professional boundaries, through impersonal and highly abstracted communication channels and reporting procedures» (Wagner&Sanders, 1993). Seeing this, designing communication processes, channels and imagery require analysis of the system as a whole in order to establish all the elements and touchpoints involved in the process. That would allow understanding the inputs that the users have to deal with when making decisions.

Interaction with an object and its technologies:

“The entrance of technology (computer languages), […] shifts the attention of ergonomics to the cognitive aspects of interaction” (Tosi, F., 2005, p.23). In the medical field, and specifically in the case-study investigated by this research, computer technologies are playing almost the leading role in the progress of the Healthcare system, but also it became in a way background of interaction due to that many medical products have a computer processor inside. Many health professionals are using ICT, either as active users or as producers of data. Some of these systems though are still in an experimental stage. Ethnotechnology is of interest as it studies the relationship and the gap between the way the technologies are used and were originally conceived by the developers (Grossen&Pochon, 1997).

The benefit of a computer screen is considered to be in clarity of displaying the important details of health data. However, the production of health data depends on the context of use and thus it is the context that defines how detailed these data should be. Here the question is not only about technological opportunities to express data in one way or another, but some ethical questions are rising. Examples are the transparency of data on the one hand, and the ability to tolerate and operate with the data (by a patient) on the other hand.

The questions of contextual communication are important here because misunderstandings and wrong conclusions made by the users could otherwise create disorder and even panic. Step by step it becomes possible to observe that logical processes in fact inevitably include emotional, subjective aspects that introduce difficulties in developing well-structured guidelines.

Functionality of an object:

«The main design problems related to the functional aspects refer to the compatibility between the physical characteristics and capabilities of the users and to the conditions and constraints imposed by the physical and organizational context in which they operate» (Tosi, F., 2005). In this case, a relative discipline is 'traditional' ergonomics that studies Human Factors, i.e. the body. But from Norman onward, the focus is not only on the effectiveness of the object but also on its efficiency and how users perceive its usability [despite its actual usability]. So-called 'perceived usability' or 'potential usability' is represented by the degree of usability that users assume an object can have where the assumptions are made through the senses: tactility, sight, hearing, etc. Regarding the design process it is interesting to consider a perceptual phenomenon of Synesthesia in which stimulation of one sensory or cognitive pathway leads to automatic experiences in a

second sensory or cognitive pathway. Thus, designing for senses would allow easier recognition of an object's function.

Errors:

Human error is implicated in about 80% of accidents, and there are various typologies of errors, such as errors in actions, control, recovery, communication, and selection. Patel and colleagues have recently argued for a new paradigm for error studies, where instead of zero error tolerance, detection and correction of a potential error is viewed as an integral part of cognitive work in a complex workplace (Patel, V. L. et al., 2010). From a design point of view, it means to plan a system that is 'aware' of human's propensity to make errors and therefore that is smart and flexible enough to foresee where and when the error may happen or to tolerate them and to help people correct the error(s).

3.2 Emotional aspects

Subjectivity:

Always taking as a reference the definition by Treccani, there is the following understanding of emotion: «*Nel linguaggio psicologico, esperienza caratterizzata da sentimenti soggettivi e variamente definibili; può essere piacevole o spiacevole ed è solitamente accompagnata da reazioni fisiche*» (In psychological language, an experience characterized by subjective and variously definable feelings; can be pleasant or unpleasant and is usually accompanied by physical reactions). Thus, emotions are the experiences that provoke physical reactions and influence actions. Regarding the medical environment, the emotional experience [of the patient] is generally quite high, as medical equipment doesn't consist of only functional aspects. It has also symbolic meanings for the patients, both positive and negative, e.g. the meaning of hope, safety, reliability, change, fear and of an unknown. Which of these meanings should be delivered to the user, how and when? How much transparency is needed in order to provide confidence and the feeling of safety, and what instead should remain covered? How could patients understand if they are getting better, and if not, what information would support them psychologically? Till which limits patients could interact with the medical equipment, its information, and impact its functionality? And finally, where are the borders of a condition which can be considered healthy? There is a conception of "New Human Factors" meaning with the adjective 'new' a new dimension of the user's needs: the subjective ones, such as perceptive pleasantness, the social, emotional and aesthetic value of the product. Jordan has developed a method which promises the possibility of attributing a "personality" to the products and of the fact that products should be considered as "living objects with which people have relationships" (Jordan, P. W., 2002). Establishing correct relationships with medical devices is one of the objectives and is impossible without considering the emotional aspects of interaction. Therefore, in some way, the question of personalization are rising. However, regarding personalization, specifically in this research that aims at testing its results on nasal ventilator Giulia, the ideal goal is not to develop guidelines for designing only an object, but to design guidelines for cognitive interaction, which is despite having common laws, is very subjective and thus represents a contradiction to the idea of guidelines, which are in their turn a standard.

Perception:

Gestalt psychology represents the basics of modern knowledge of visual perception. R. Arnheim (1974) in his book "Art and Visual Perception" describes all the elements that play an important role in visual perception and their interrelations, among which: equilibrium, color, light, form, shape, space, development, dynamics, and movement. This systemization provides rules for building a correct visual composition that allows easier reading and understanding of the information that it carries. American psychologist J. J.

Gibson has influenced the way of understanding of the visual perception. According to his theory of Affordance, the perception of the environment leads to a course of action. Examples of explicit affordances include buttons for pushing, knobs for turning, handles for pulling, etc. Based on Gestalt theories, Affordance Theory has various implications for design, human-computer interaction, ergonomics, visualization, etc. (Gibson, J. J., 1966, Gibson, J. J., 1950). Having seen this, it is possible to say that the Gestalt theory and Affordance theory contributes to the design process with the useful criteria to consider in order to develop a correct visual communication, both in terms of information communication and an overall object's perception, and to evaluate the design work.

Conclusions

As it was mentioned previously, the objective of the present research is to develop tools and/or guidelines for designing a correct physical and cognitive interaction with the Medical devices. In order to reach that objective, the research interests have been divided into three areas of knowledge: an overview of the Healthcare scenario, the study of the Cognitive Ergonomics discipline to then systemize features and aspects of cognitive interaction, and finally to analyze the role of Design in Healthcare sector in order to understand its possible contribution and eventually to use it as a method and an approach to research.

In the second paragraph, a general overview of the three areas of interest was proposed in order to frame the context of the action of the present research. In particular, some evidence regarding healthcare scenario was highlighted, that describe the healthcare sector in the phase of its transformation that brings out the necessity in innovative solutions adaptable to these transformations. On the other hand, a literature review on the discipline of Cognitive Ergonomics has been done in order to extract its features that are necessary to consider for designing ergonomically correct interaction with an object. Eventually, after seeing the role of design in Healthcare, its methods, approaches, and contributions, Design Thinking is chosen to apply to this research as the method for approaching the interdisciplinarity.

In the third paragraph, the analysis of cognitive ergonomics features was done in order to see what might be a design objective regarding each feature. Thus, the features were divided into two groups of aspects: rational and emotional. According to this division and to the definitions of 'rational' and 'emotional', the features like Operator's Functional State and mental workload, decision-making, errors, functionality of the object, interaction with the object and its technologies, were grouped as Rational aspects of cognitive interaction, and subjectivity and perception as Emotional. Based on this division, the following design questions and objectives were set as the first proposal for the future guidelines for designing an ergonomically correct interaction with Medical Devices (see Figure 3):

1. Optimize tasks to perform for the user in terms of balancing the mental workload at the moment and the resources available;
2. Define all the elements of the system in order to evaluate the inputs that the user has to deal with when in a situation of decision-making;
3. Ensure the flexibility of the system in order to make it errors' tolerant;
4. Check the usability and the visual communication of the information through the laws of visual perception;
5. Help users to establish correct relationships by taking into account the subjectivity of people's cognition.

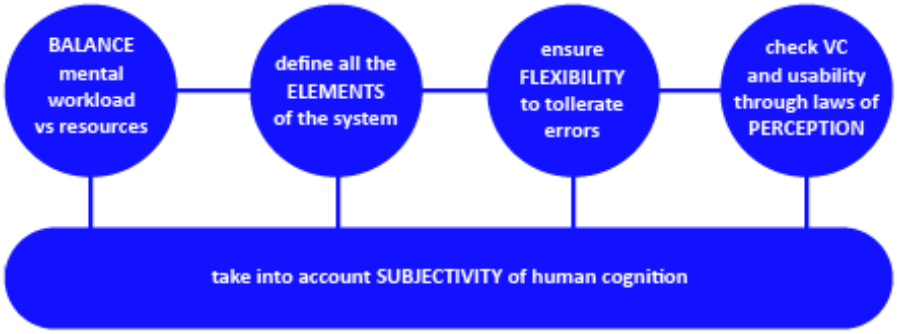

Figure 3. First proposal for the design guidelines: questions to consider

The next step of the present research would be to test the validity of this proposal through Design Through Research method applied to the Product nasal ventilator case-study provided by the Company and to define the practical structure of each step.

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