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Systemic innovation in sustainable design of medical devices

Silvia Barbero[a], Amina Pereno[a*], Paolo Tamborrini[a]

[a] Politecnico di Torino, Department of Architecture and Design
*Corresponding author e-mail: amina.pereno@polito.it

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Abstract: The specific nature and the size of the healthcare sector make its impact on the environment very significant. Over the past years, interest in Sustainable Healthcare has grown globally, and an increasing number of companies is addressing a discipline, Sustainable Design, that is relatively new for the health sector. Design for healthcare must face significant challenges: from the technical, regulatory and ethical complexity, to the lack of a methodological history and the need for an interdisciplinary design approach. The present work shows the methodology and results of an interdisciplinary research on sustainable design for chronic haemodialysis, focusing on the dialysis equipment. Starting from Systemic Design methodology, the equipment has been analysed both as an autonomous system (component and functioning analysis) and as an interacting system (device analysis, interaction, ward management). This allowed to define the main issues and potentialities according to maintenance and end of life, flows management and interactive dynamics.

Keywords: sustainable healthcare, systemic design, medical device design, environmental sustainability, eco-innovation

1. Introduction

The specific nature and the size (on average about 10% of GDP of Western Europe countries) (WorldBank, 2014; World Health Organization, 2016) of the healthcare sector make its impact on the environment very significant: from waste production, to the increasing use of chemicals and disposable materials, from pharmaceuticals in the environment to medical infectious waste and radioactive pollution. Over the past years, interest in Sustainable Healthcare has grown globally; this is not only due to the widespread attention to the environment but also to the need to achieve greater economic sustainability in medical care and a wider ethical responsibility. Nowadays, several programmes sponsored by the European National Health Services are promoting new strategies and policies in the field of Sustainable Healthcare (Jamieson et al, 2015), encouraged by international organizations and associations which bring together health stakeholders, companies and other public and private players. Especially, new Green Public Procurement strategies for healthcare try to meet the public and the commercial interest of companies (Oruezabala, & Rico, 2012). Indeed, the

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increased request for environmental and economic sustainability of health systems opens up new commercial opportunities for those companies which can provide more sustainable products, services, and systems. So more and more companies are moving in this direction, addressing a discipline, sustainable design, that is relatively new for the health sector. Therefore, design plays a central role towards sustainable innovation in healthcare (Jones, 2013) and must face major challenges. First, the technical, regulatory and ethical complexity of products and services for healthcare; secondly, the lack of a methodological history in this sector (considering that few projects and research addressed environmental sustainability in healthcare); lastly, the need for an interdisciplinary design methodology and the difficulties deriving from it.

The present work shows the methodological and design results of an interdisciplinary research on sustainable design for chronic haemodialysis. The project aimed at defining the main environmental issues of this chronic treatment, and lay down specific eco-guidelines for dialysis packaging, products, and equipment. This paper focuses on the research carried out on the dialysis equipment: starting from a Systemic Design methodology (Bistagnino, 2011; Jones, 2014), the equipment has been analysed both as an autonomous system (component and functioning analysis) and as an interacting system (device analysis, interaction, and management within different contexts). The analysis has been carried out in collaboration with a team of nephrologists (San Luigi Gonzaga Hospital, Department of Clinical and Biological Sciences, University of Torino) and mechanical engineers (Department of Mechanical and Aerospace Engineering, Politecnico di Torino). This allowed to define the main issues and potentialities according to maintenance and end of life (components layout and accessibility), flows management (layout analysis in relation to fluid flows), and interaction during maintenance. The complexity of healthcare needs special attention as regards the context: a medical device must interact and adapt to different final users (technicians, healthcare staff, and patients), health infrastructures (water supply, material supply, device management), and different regional and national organisational structures). On-field analysis has been carried out in three Dialysis Units based in different European countries: San Luigi Gonzaga University Hospital (Turin, Italy), Skåne University Hospital (Malmö, Sweden), and Frederiksberg Hospital (Frederiksberg, Denmark). The on-field analysis has allowed determining the influences of the context of the medical device design.

The main purpose of this paper is to show the analysis carried out on the haemodialysis equipment to define a methodology that can be effectively applied for designing complex products and systems in healthcare.

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2. Methodology

Chronic Haemodialysis is a life-saving treatment for people who lost the function of kidneys: this kind of renal replacement therapy includes different methods according to the patient's disease. This means using different types of disposable products, packaging and, sometimes, specific machines. The present research has started from the waste analysis (packaging and disposable products) of three types of dialysis (in-center bicarbonate dialysis, ultrafiltration home dialysis, in-center hemodiafiltration) (Pereno, Nazha, & Tamborrini, 2015; Piccoli et al., 2015). While there are many suppliers of dialysis and several types of disposable products, on the contrary, there are few major manufacturers of dialysis equipment at a global level. Because of its cost and complexity, the dialysis equipment is usually designed to perform different types of treatment and to adapt to different contexts and infrastructures. For this reason, the present study has focused on the analysis of an equipment that could be a valuable example of a commonly used dialysis machine. FRESENIUS 5008,

by Fresenius Medical Care, is a haemodialysis equipment that can perform bicarbonate dialysis, single-needle dialysis, and hemodiafiltration, just by setting different parameters and using different disposable products.

2.1 Theoretical framework: Systemic Design

One of the main problem Design has to face in the healthcare sector, is the lack of a methodological history regarding environmental sustainability. A big challenge in the present research was the choice of an effective methodological approach to tackling the complexity of this topic.

While no common understanding of "Systemic Design" exists, this pretty new design discipline aims at integrating systems thinking and human-centered design to support designers working on complex design projects (Systemic Design Research Network, 2017). As Peter Jones (2014) explained::

> "Systemic design is distinguished from service or experience design in terms of scale, social complexity and integration. Systemic design is concerned with higher order systems that encompass multiple subsystems. By integrating systems thinking and its methods, systemic design brings human-centered design to complex, multi-stakeholder service systems as those found in industrial networks, transportation, medicine and healthcare."

According to Luigi Bistagnino (2011), Systemic Design also brings about "a change in the approach to the output of the production systems", turning it from a problem into a resource (new input for another system). Therefore, a systemic approach can help designers to face complex issues, taking into account both users (human-centred design) and environment (principle of outputs> inputs).

The discipline of Systemic Design integrates different design tools that have been borrowed from other approaches to product and service design. Specifically, the systemic perspective brings to an evolution of methodologies concerning sustainable product design. Design for Disassembly is a well established and accepted design approach that aims to "design a product that can be readily dismantled at the end of its life and thus optimise the reuse, remanufacturing or recycling of materials, components and sub-assemblies" (Bogue, 2007). The ease of disassembly deeply affects the environmental sustainability of a product, focusing on its end of life. By applying systems thinking and human-centered design principles to this approach, we can go further the end of life, including the whole life cycle. Starting from the components (materials, connections, functioning, product architecture) and the interaction of the user(s) with the product (needs, gesture, routines), we can design new products that are easy to use, maintain and disassembly. Systemic Design shapes the product starting from the relationship among the components and the users (Bistagnino, Virano, & Marino, 2008), taking into account the material flows that occur within a specific context (inputs and outputs). This allows designing a more efficient product system, promoting the adoption of sustainable components and technologies.

As argued above, Systemic Design is especially suitable to manage design projects in complex systems. The presented methodology has already been applied to several projects concerning the home environment and household appliances (Fiore et al, 2016), but in this research, a further step was needed to face the complexity of healthcare and medical equipment.

The complex nature of biomedical equipment exceeds many other sectors, from a technical, regulatory and ethical point of view. First, designers have to manage a product that is not commonly used in the daily life, so they need to acquire specific technical skills and medical lexicons to cope with this particular kind of project. Secondly, biomedical companies spent many years developing, testing and patenting the components of the medical equipment, which are therefore not easily

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replaceable with other solutions. Furthermore, several disposable products are needed within the medical treatment: every modification of the equipment also affects the whole product system. Finally, a medical device takes from 3 to 7 years before being placed on the market (Fargen et al, 2013; Christin, 2012), this is not only due to its design complexity but also because every change requires new medical testing and approvals. The more it will change, the longer it will take to fulfil all the conditions and get on the market.

For this reason, the present research has carried out the equipment analysis according to a Systemic Design methodology but, unlike other sectors, it aimed at reaching a better understanding of components and flows to design a new product architecture and layout while leaving the current components unchanged.

In the following paragraphs, the Systemic Design approach to medical device design is described in detail. The analysis of the dialysis equipment has focused on components and materials (disassembly analysis), the type and ease kind of access to the device by different users (accessibility and interaction), and the definition of inputs and outputs (flows analysis). Finally, the influences of the context on the medical device design have been identified from a European perspective (holistic diagnosis).

The study was performed in collaboration with the team of the San Luigi Gonzaga Hospital (Department of Clinical and Biological Sciences, University of Torino) and the team of the Department of Mechanical and Aerospace Engineering (Politecnico di Torino). We also got technical advice from ACTEM technicians (partner of Fresenius Medical Care).

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2.2 Disassembly analysis: components and materials

This analysis is based on the disassembly of the product. The dialysis equipment has been divided into 10 macro-components, according to their function and position. Each macro-component has been completely disassembled, and each sub-component has been identified by an identification code that designates its function and the progressive number (e.g. CD1 = Conductivity Cell n. 1; H02 = Hydraulics component n.2, etc.).

The Disassembly Analysis (figure 1) aims at reaching some important goals:

1. Full understanding of the equipment concerned, its operation and its components.
2. Identifying the components that are easy or difficult to disassembly, because of accessibility or type of joints (reversible or irreversible). The identification of the needed tools is necessary to determine the ease of disassembly. In the graphic displays of Disassembly Analysis, we used a basic colour coding (green – easy, orange – medium, red – hard) to identify the most critical components, while the tools we used to disassemble the components, are indicated with the help of icons.
3. Defining the material composition of the dialysis equipment, and understanding the ease of separation of different materials in end of life. This directly affects the ease of recycling and the disposal of the product itself. A summary table shows, for each component (identified by its code), the materials that make it up and their relative weights. This allows defining which are the single-material components and the multi-material ones, and which are not recyclable or have to be separately sorted (e.g. WEEE). So we can understand which materials make the equipment up and in what quantity.

Overall, the Disassembly Analysis allows defining the most critical issues regarding environmental sustainability, considering both the maintenance of the equipment (ease of replacement, ease of separation of sub-components) and the disposal at the end of its useful lifespan (ease of disassembly according to different materials).

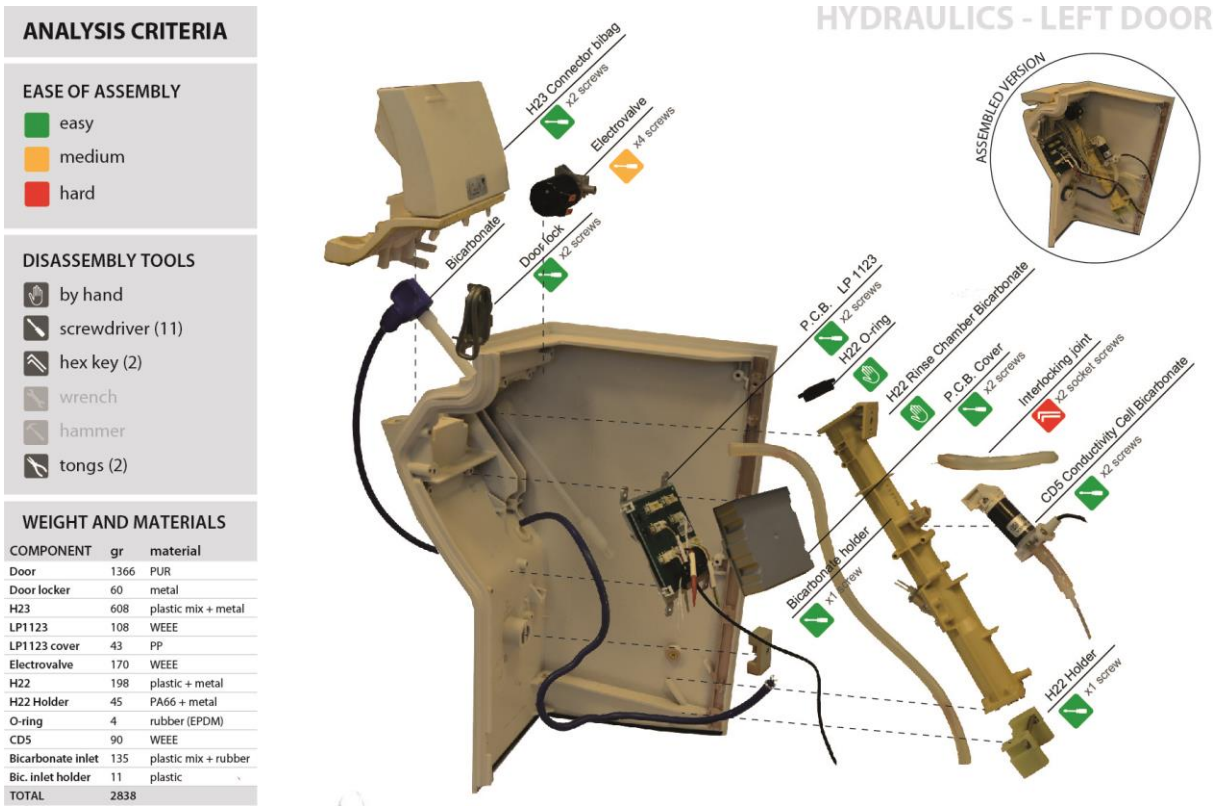


Figure 1. Example of Disassembly Analysis. The disassembly of a hydraulics macro-component is showed through a photographic exploded view. The tools needed to disassembly are visualized through icons, while the ease of assembly is indicated by means of a colour coding. The materials and weights of different components are summed up in a table.

2.3 Accessibility and interaction

The second part of the analysis brings together the Disassembly Analysis and the on-the-field analysis (concerning routines and users' interaction) to define the ease of access to macro- and sub-components by different users (maintenance technicians, healthcare staff, patients).

In the graphics displays (figure 2), the colour coding is the same of the Disassembly Analysis (green – easy, orange – medium, red – hard). However, it does not identify one single component but groups of components according to their function. The analysis of accessibility, carried out during disassembly, is verified by the on-the-field analysis that takes into account treatment routine (healthcare staff and patients) and routine preventive maintenance (technicians); this allows to understand frequency and type of use of different groups of components.

This analysis aims at establishing a hierarchy regarding accessibility to functional components, by comparing the ease of access with the component functionality. The difficulties in accessing a component that should be daily used by healthcare staff represent a design problem to solve. Conversely, the difficult access to a delicate internal component may be a safety choice to take into account also in future projects.

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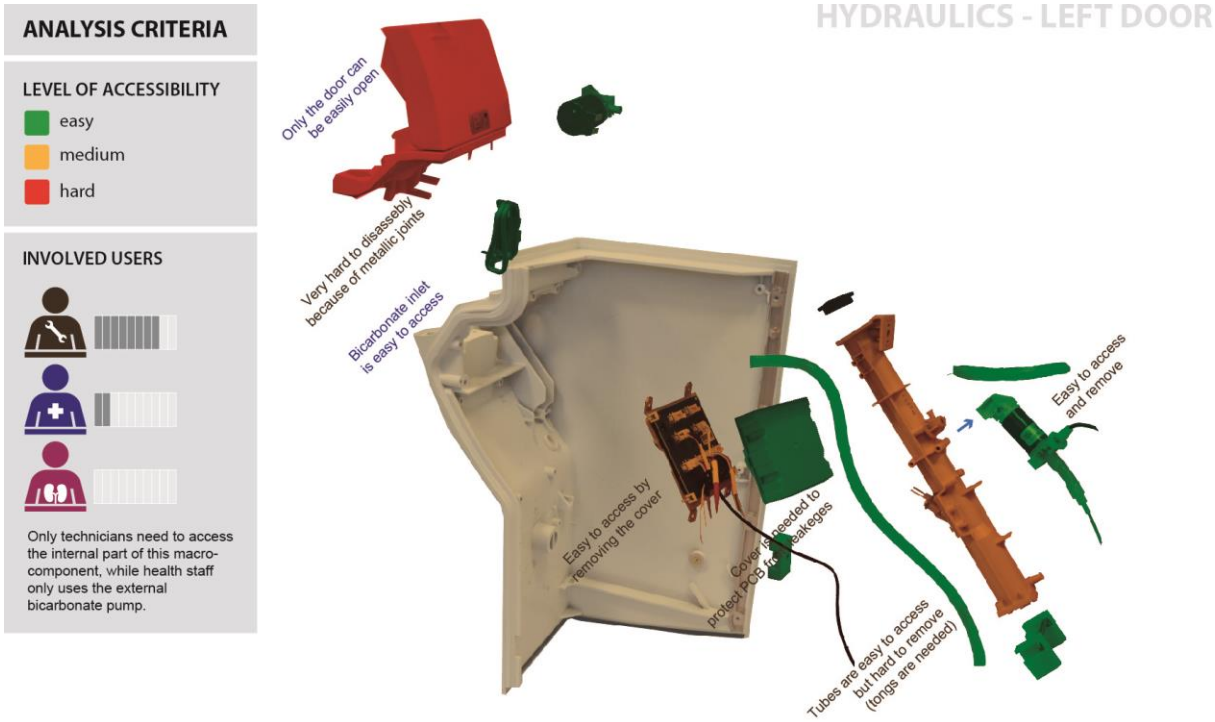


Figure 2. Example of accessibility and interaction analysis. The colour coding indicates the level of accessibility, and specific notes highlight the most critical components. The involvement of different users is stated by a bar indicator.

2.4 Flows analysis

The analysis of the inputs and outputs of the process aims at highlighting critical issues and potentialities from the points of view of environmental sustainability and usability. The analysis is usually carried out through the creation of a general scheme, which sums up flows and functions of the product. Then, an essential scheme is designed to simplify the product features, stressing the main components and flows.

When dealing with a medical equipment, the definition of general and essential schemes (figure 3) is possible but considerably more complex; therefore two intermediate steps are needed. The general scheme of the treatment process is accomplished through single schemes for each macro-component. This visualization, unlike the traditional methodology, shows the current layout of components: this allows designers to use the scheme to interpret the current situation and discuss with the other members of the interdisciplinary team.

Then, it is possible to design an essential scheme for each macro-component, going beyond the original layout. The sum of all the essential schemes is an overall essential scheme of the medical equipment, which integrates the functions of the disposable products. In some macro-components, disposable products are real external components of the equipment (e.g. the Extra-Corporeal Blood Circuit Module employs filters and arterial-venous bloodlines that, because of technical and sanitary issues, have to be disposable. The equipment manages these single-use components through peristaltic pumps and temperature sensors).

The nomenclature through alphanumeric codes used in the Disassembly Analysis is also employed in the general and essential schemes, as designers have to design a new layout while keeping the same

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base components.

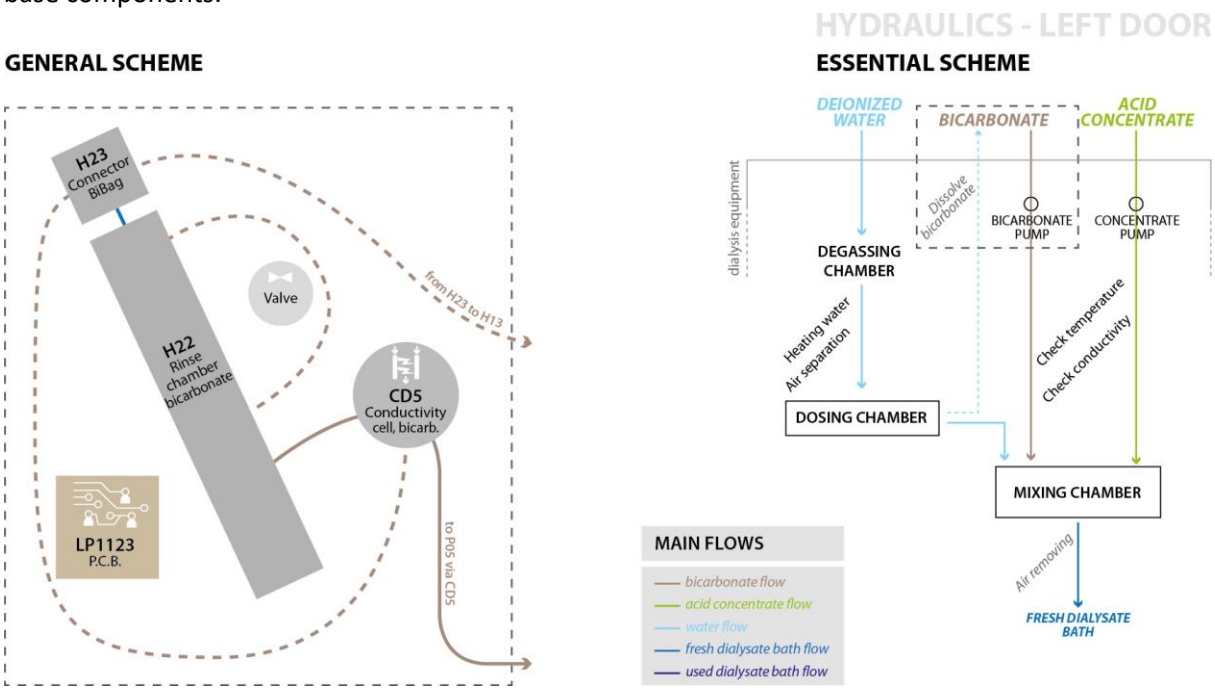


Figure 3. Example of general scheme (on the left) and essential scheme (on the right). The essential scheme brings together all the hydraulics macro-components that mix different material flows to obtain the fresh dialysate bath.

2.5 Holistic diagnosis: from users to wider scenarios

The holistic diagnosis has been carried out in parallel with disassembly analysis, focusing on the contexts in which the medical equipment is used. In this case, three different case studies have been analysed and compared: this was essential to assess and highlight the importance of the context in the healthcare sector. Since we are mainly dealing with the public sector, national and regional policies and organizations (wide scenario) deeply affect the hospitals and wards in which treatments take place (local scenario) and, therefore, the products and equipment managed by final users (specific scenario).

In each of the three scenarios (figure 4), special features are observed and reported:

1. Wide scenario: national and regional strategies for environmental sustainability in healthcare; green public procurement schemes; healthcare organization.
2. Local scenario: hospital and ward management; persons responsible for environmental sustainability; treatment routines.
3. Specific scenario: product requirements for purchasing; usability requirements.

By combining all the scenarios, it is possible to define a composite scenario in which the medical equipment will be purchased, used and disposed of.

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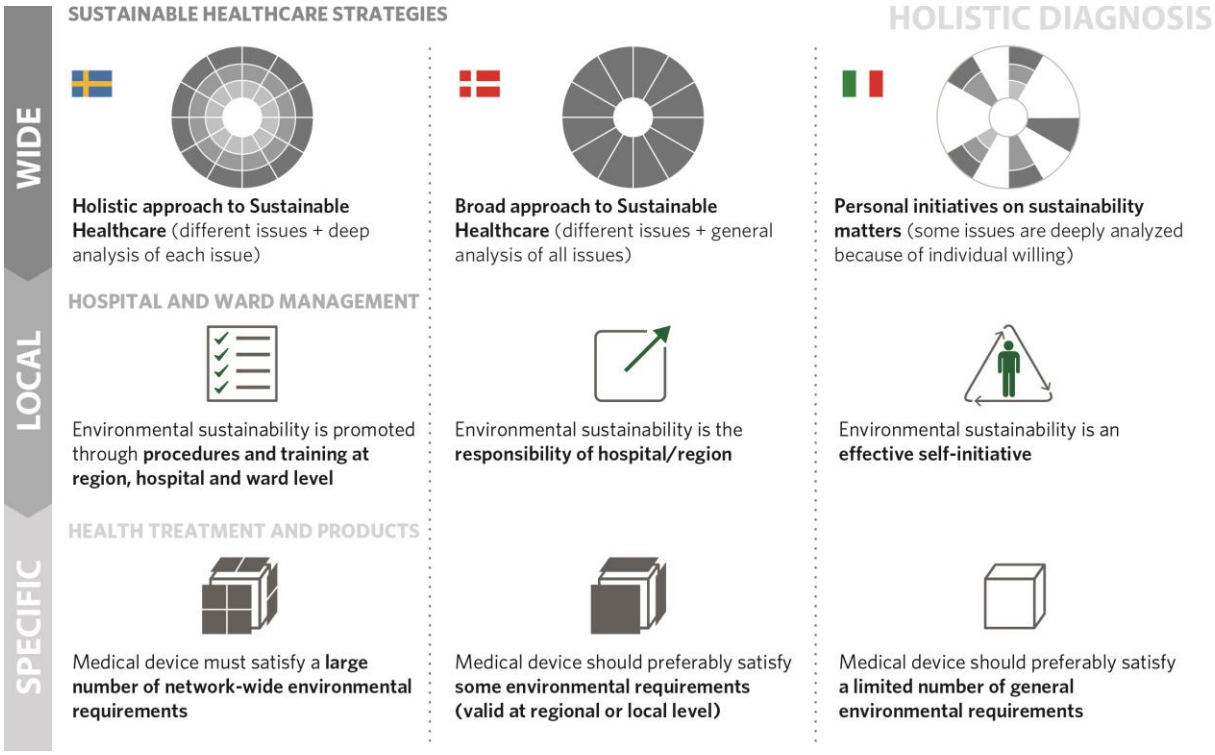


Figure 4. Summary of the holistic diagnosis carried out within the research on chronic haemodialysis.

3. Results

In this work, we sought to establish a methodology for the analysis of medical equipment to design more sustainable solutions for the healthcare sector.

The result of this work has been twofold: on the one hand, we defined the main requirements to improve the environmental sustainability of haemodialysis treatment, integrating equipment and disposable products and meeting the users' needs (technicians, healthcare staff, patients) in an environmentally sustainable way. On the other hand, the methodology we showed has been tested, revised and developed to be applied to other types of medical devices. Design has to face significant environmental challenges in the healthcare sector and needs specific methodologies to tackle them.

The standard Systemic Design Methodology (figure 5) is particularly suitable for analysing and designing products in a more sustainable and effective way. However, the systemic complexity of medical equipment created a need for improved implementations of the existing methodology. So in the present work, the methodology has been updated (figure 6), aiming at proposing a new methodological framework to address sustainable healthcare by design.

The standard methodology (SM) and the updated methodology (UM) are broadly similar, but we can highlight four main differences:

- he first difference concerns the analysis workflow. In the SM the analysis starts from the product as a whole, then macro-components are identified and analysed together before designing the general scheme. In the UM the complexity of medical equipment requires a first step in which the product is divided into several macro-components according to their function, then each of them is individually analysed.
- The second difference is the level of knowledge acquired through the different steps of analysis. In the SM, designers already have a basic knowledge of the product that

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allows them to improve their information quickly so that they can design general and essential schemes having an in-depth understanding of the product. In the healthcare sector, industrial designers often have little knowledge about the medical equipment; thus the first phase of the UM includes the division of the device in macro-components and the proper disassembly of each of them. This lets the designers reach a basic knowledge of the device. Only the following steps of analysis and the design of single general schemes allows building up better understanding of the topic.

- The third difference is the link to the current layout: in the SM, after the first phase in which the existing product is analysed, it comes to general and essential schemes that are focused on function, regardless of the pre-existing shape. When dealing with medical equipment, the general scheme keeps a close connection with the existing product: it serves as a kind of map that allows the design team to share information and knowledge about the current device layout. After in-depth knowledge has been gained on the device function and components, the essential scheme is designed to create an abstraction of the real product, underlining material and interactive flows that can bring the project to a completely new definition of internal layout and external shape.
- The fourth substantial difference is the context analysis: in the SM, context is taken into account when input-output flows are analysed (general schemes) and their quality and sourcing is assessed to relate the product and the local context (mainly focusing on final users and their cultural background). In the UM, holistic diagnosis is a key point of the analysis, and it addresses different contexts. Starting from international and national strategies (wide level), designers investigate the local level (regional and hospital organisations) and then focus on the specific level (final users – patients, health staff, technicians – and device requirements).

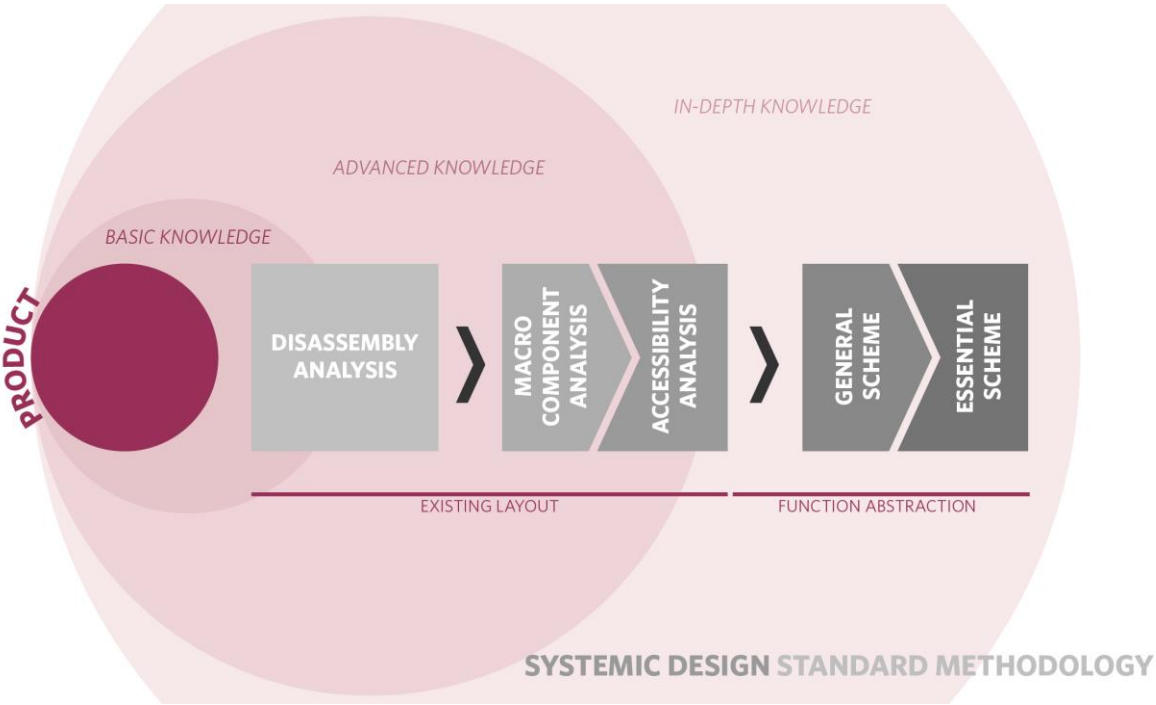


Figure 5. Scheme of the standard Systemic Design approach to product.

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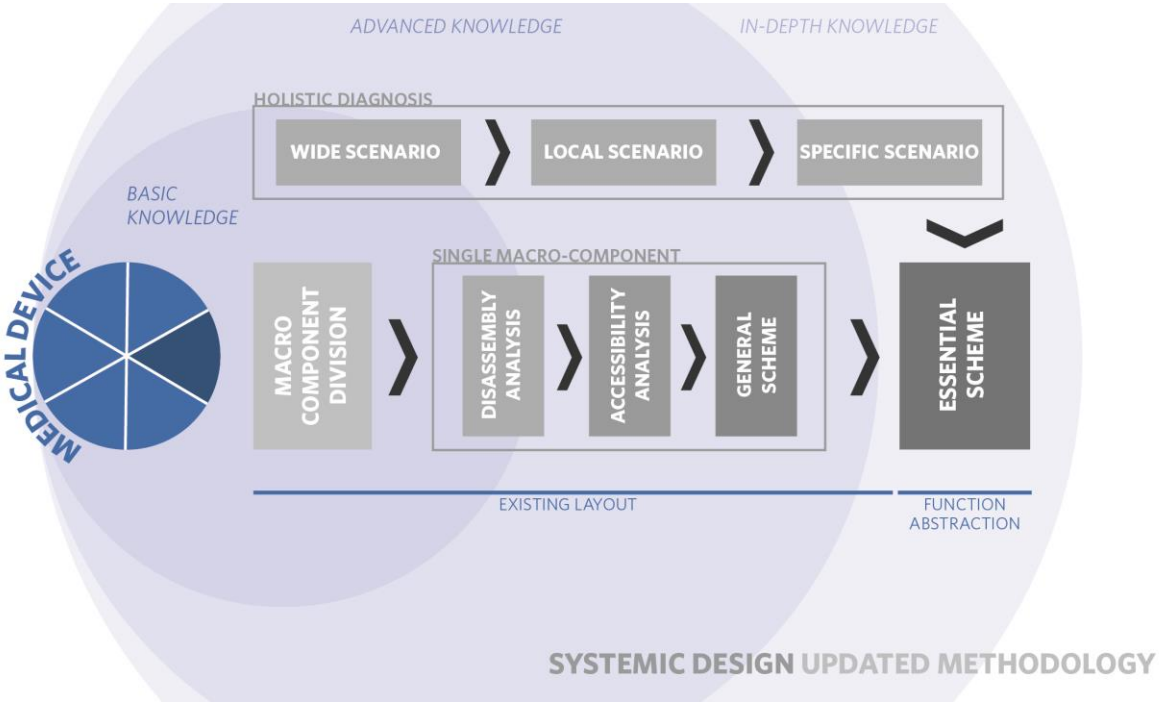


Figure 6. Scheme of the updated Systemic Design methodology to medical equipment analysis.

4. Conclusions

The healthcare sector is facing an increasing demand for environmentally and economically friendly solutions. This provides new opportunities for companies which can provide more sustainable products, services, and systems. So the market is moving towards this direction, motivating companies to take a particular interest in sustainable design.

Many studies in recent years have investigated the environmental impacts of the health sector, focusing on new paths to improve healthcare facilities (Zadeh et al., 2016), procurement (Chiarini & Vagnoni, 2016) and education (Richardson et al., 2014). No work has analysed the application of sustainable design methods to medical products: since this discipline is relatively new for the health sector, specific methodologies are needed to face the complexity and multi-disciplinarity of healthcare.

This study aims to face the challenge of environmental sustainability of medical equipment from a systemic design perspective, providing a new method to analyse and redesign medical devices.

Our results provide a clear definition of the main steps to take to analyse complex devices from an environmental and functional point of view. This allows designers to define specific requirements that address both the device investigation and the on-the-field analysis. The presented methodology starts from the standard Systemic Design methodology, updating it according to the needs of the healthcare sector.

This methodology will be verified in future practical application to other types of medical devices, making a comparison between different complex products from the same area. In the short term, further work should focus on the design of a new chronic haemodialysis system, that will bring together dialysis equipment, disposable products, and packaging requirements.

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About the Authors:

Amina Pereno is Ph.D. candidate in Management, Production and Design at Politecnico di Torino. She has been visiting researcher at TEM at Lund University (Sweden), and she is collaborating with the Nordic Center for Sustainable Healthcare (Sweden) on topics related to sustainable design for healthcare.

Silvia Barbero Ph.D., is Assistant Professor at Politecnico di Torino. She has a PhD from the Departments of Management and Production Engineering, POLITO (Italy) and the International Institute for Industrial Environmental Economics, Lund University (Sweden). She is lecturer of "Product Environmental Requirements" at POLITO.

Paolo Tamborrini is architect and Associate Professor of Design. Head of the Design School at Politecnico di Torino (Italy); founder and scientific coordinator of the Systemic Innovation Design Network (SyInDe). Editor about innovation design, eco-design and sustainability for the major design magazines.

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