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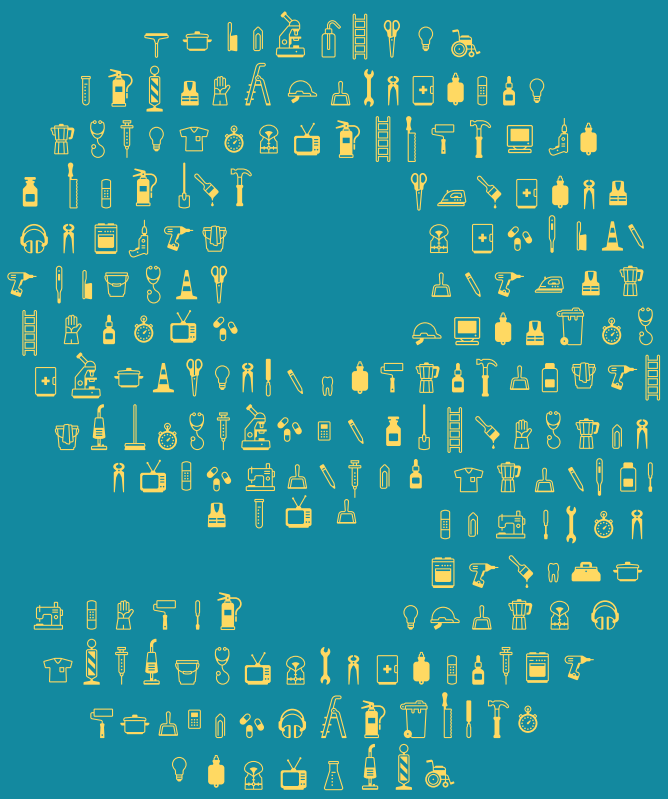

- RETHINKING NEONATAL CARE
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- ENHANCING HOSPITAL NAVIGATION THROUGH GAMIFICATION
- NEIGHBORHOOD EDUCATIONAL CENTER
- A CLASSROOM TAILORED TO STUDENTS WITH CHRONIC MEDICAL CONDITIONS

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RIVISTA ITALIANA DI ERGONOMIA

THE RIVISTA ITALIANA DI ERGONOMIA, *of the S.I.E. - Italian Society of Ergonomics, is a scientific journal that operates nationally and internationally for the promotion and development of ergonomics and the study of human factors, and the dissemination and systematization of knowledge and experiences related to the ergonomic approach, in close relationship with the social, environmental and productive realities where human beings, operate and live, coherently with the goals of the SIE.*

Supported by an international scientific committee and using a double-blind reviewing process, the journal publishes original contributions from research and applications on ergonomic issues, in its various aspects and related to the different contexts and human activities.

The RIVISTA ITALIANA DI ERGONOMIA *is aimed at ergonomic professionals and all those interested in applying the principles and methods of ergonomics / human factors in the design, planning and management of technical and social systems, in work or in leisure.*

INDEX

Rethinking neonatal care: Addressing risks and improving safety in ventilation practices

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Keywords: Medication errors, Healthcare Design, Human-Centred Design, Usability of Medical Devices, Neonatal portable ventilator

Abstract

This study, conducted at the Meyer Children's Hospital in Florence, addresses the challenges of neonatal care, with a particular focus on mechanical ventilation, an area with a high risk of errors. Despite advanced technologies, newborns are exposed to risks three times greater than adults due to the complexity of treatments and equipment used. One of the main issues identified is related to the use of lung ventilators, which can lead to human errors and physiological complications. The objective of the research was to improve both the well-being of the small patients and the working conditions of the medical staff. By applying Human-Centred Design methods, user needs and usability issues of existing ventilators were analysed. The analysis involved direct observations, interviews, and questionnaires to identify difficulties related to the digital interface and the organization of care phases. The results led to the design of the Andy ventilator, which stands out for its user-friendly interface, versatility, and ease of transport. Andy reduces risk factors by allowing continuous use without disconnecting the patient. This innovation not only enhances the safety and effectiveness of

ventilatory assistance but has also been awarded the iF DESIGN TALENT AWARD 2022, highlighting the importance of ergonomics and user-centred design in the healthcare field.

Introduction

Research and innovation are fundamental in addressing paediatric healthcare challenges, especially in critical contexts such as Neonatal Intensive Care Units (NICUs). The continuous evolution of clinical issues, enrichment of scientific knowledge, and adoption of multidisciplinary approaches pave the way for new solutions that can revolutionize paediatric patient care.

A central aspect of this innovation is adopting digital technologies, which are essential for improving medical devices' safety and effectiveness. These devices must be designed to meet the needs of paediatric patients, healthcare professionals, and families, ensuring increasingly intuitive and safe solutions (Tosi & Rinaldi, 2015; Iacono et al., 2019).

The complexity of care flows can lead to errors in product use and understanding of digital interfaces, creating risks to patient safety. A human-centred design approach, which includes the application of ergonomic methodologies, helps anticipate risks and simplify interactions with devices, reducing operational errors.

Interdisciplinary collaborations between designers, engineers, and doctors are crucial for developing practical solutions that address the complex challenges related to child health, optimize workflows, and improve the quality of care. Additionally, the inclusion and involvement of users in the design process are key factors in creating relevant and effective devices. A participatory approach increases user satisfaction and improves clinical outcomes. Moreover, integrating artificial intelligence and machine learning presents an excellent opportunity to optimize NICU processes. Recent studies (Tscholl et al., 2018) show that these technologies can improve decision-making accuracy and reduce errors through real-time data analysis.

A concrete example of applying usability and safety evaluation methodologies typical of Human-Centred Design (HCD) and User Experience (UX) has been developed at the Meyer Children's Hospital in Florence. The study presented in this article aimed to improve paediatric patients' well-being and medical staff's working conditions. By focusing on facilitating interaction and simplifying procedures, the goal was to minimize the risk of operational errors, thereby helping

create a safer and more efficient healthcare environment. The results highlight the importance of design and innovation as strategic levers for improving paediatric care and the safety of young patients, contributing to building a better future for child healthcare.

Clinical risks and safety in neonatal ventilation: a critical analysis

In recent years, the growing focus on risks and harm in healthcare settings has brought the topic of medical errors to the forefront as part of the broader issue of clinical risk. A widely cited 2016 study conducted by Johns Hopkins University classified medical errors as the third leading cause of death in the United States, bringing public attention to the frequency and seriousness of these preventable incidents. In particular, a 2020 study estimates that 6% of hospitalized patients suffer harm from medical errors, often preventable, especially in critical areas like intensive care, where the rate of preventable events rises to 18%, with higher risks associated with invasive procedures, medication errors, and misdiagnoses (Atanasov et al., 2020). In healthcare, unlike other fields such as aviation and nuclear power plants, implementing human factors engineering and ergonomic techniques remains limited, making it challenging to reduce operational errors (Brixey et al., 2002). This issue is particularly critical in paediatrics and in Neonatal Intensive Care Units (NICUs), where newborns face a risk three times higher than adults for complications related to medication administration and respiratory care (Kaushal et al., 2001). Respiratory diseases are one of the leading causes of hospitalization in NICUs, significantly contributing to neonatal mortality and resulting in a frequent incidence of bronchopulmonary dysplasia (BPD) in low-birth-weight infants who require specialized ventilatory support to reduce complications and improve survival (Jacob et al., 2015; Klingenberg et al., 2017; Dyer, 2019). Despite technological advancements, mechanical ventilation exposes patients to the risks of lung damage, infections, and physiological complications.

The WHO suggests a systemic approach to improving patient safety, which includes effective communication among healthcare teams, proper workload management, and standardization of safety protocols. Particular attention should be given to “human factors”, such as cognitive overload and operator fatigue, contributing to errors. To reduce mortality related to healthcare errors, healthcare providers must adopt well-designed technological solutions, streamlined pro-

cesses, and continuous staff training.
Studies show that healthcare incidents are often linked to human errors and organizational and device design issues, creating latent errors and compromising patient safety (Ward & Clarkson, 2004; Derrico et al., 2009; Drews, 2012). As highlighted by the Center for Devices and Radiological Health (CDRH), poor device design and ignorance of human factors can lead to serious incidents, including injuries and deaths. Specifically, ergonomic and usability deficiencies in medical devices used in NICUs can exacerbate risks associated with using and understanding digital interfaces (Iacono et al., 2019). To improve the safety and effectiveness of devices, designers must adopt a holistic design approach that considers the dynamics of use in intensive care settings and during intra- and inter-hospital transportation.

Methodology

The study conducted at the Meyer Children's Hospital in Florence was based on the use of theoretical and practical methodologies from Ergonomics for Design (Tosi, 2020), explicitly following the principles of Human-Centered Design (HCD) and User Experience (UX). These approaches allowed for managing and analysing the complexity of the clinical context, ensuring the centrality of the human factor and reducing the risk of "adverse effects" linked to improper use of devices, with benefits for patient safety, efficiency, and health. By using data collected directly from individuals in their real work environments, the study enabled the development of design solutions to address the daily challenges faced by healthcare staff. The research process included the direct involvement of various professionals (neonatologists, paediatricians, nurses, and respiratory therapists) working in Neonatal Transport and the use of ventilators, focusing on their needs and expectations and the specific skills related to product use.
The main phases of the research were as follows:

1. Definition of user profiles
2. Evaluate the ventilators in use
3. Data analysis
4. Development of concepts and intervention scenarios

Phase 1: Definition of user profiles

The first phase of the research identified the various users involved in the neonatal care process, from those who directly benefit from the treatment to the professionals and families who support the new-

born. Four user groups were identified:

1. The **beneficiary user** is the preterm newborn or one with specific medical conditions.
2. **Primary users** are medical personnel directly responsible for the care, such as neonatologists, paediatricians, specialized nurses, and respiratory therapists.
3. **Secondary users** are support figures such as volunteers and healthcare staff.
4. **Indirect users** are the newborn's parents.

This analysis allowed for a deeper understanding of each user's role and interactions with the ventilator, detailing their specific activities. For example, neonatologists assess and set the ventilation modes, paediatricians monitor respiratory parameters and care for the newborn, and nurses manage medication administration and device organization. Respiratory therapists analyse oxygenation levels to implement the necessary therapies, and support staff help strengthen the bond between the newborn and the parents. This phase highlighted critical interactions and challenges related to ventilator use, supporting a design approach centred on the real needs of the different users.

Phase 2: Evaluate the ventilators in use

The next phase of the research evaluated neonatal ventilation services and devices in use, specifically focusing on neonatal ventilators' usability in the ward and during transport. Different evaluation methods involving users (User Trials) were used to collect practical data useful for redesign, analyse critical issues, and suggest improvements.

1. Direct observations (Stanton et al., 2014). Through observation sessions in the field, researchers recorded staff actions and behaviours during ventilator use. This analysis involved photographic and video recordings, allowing for accurate documentation of the operator-device interaction.
2. Semi-structured interviews (Patton, 2015). Interviews with neonatologists, nurses, and technicians allowed it to understand the needs, difficulties, and intuitions regarding ventilator use. These interviews revealed hidden needs and operational critical issues that often escape direct observation.
3. Questionnaires (Wilson & Sharples, 2015). These were submitted to a targeted sample (7 neonatologists and 9 nurses). The questionnaires measured satisfaction and collected opinions through a 5-point Likert scale and open-ended questions. This facilitated

the collection of quantitative and qualitative data to evaluate the staff's experiences in the ward or during transport. Significant statistical data was obtained by administering predetermined items.

4. Scenarios (Hanington & Martin, 2019), workflow (Nikookar et al., 2013) and Task Analysis (Tosi, 2020). These allowed us to visualise the workflow in distinct contexts, such as the ward and transport. Thanks to tools such as personas and storyboards, it was possible to represent the activities and objectives of the users in a detailed way (see Fig. 1); in the specific case of neonatal ventilation, the objectives and activities were summarised in 3 steps: preparation, use, recovery, highlighting the problems of interaction with the device.
5. User journey maps (Hanington & Martin, 2019). Maps, tracing the users' actions, emotions and perceptions in each interaction phase, offered a complete view of the user experience. This approach revealed critical points and opportunities to improve the interaction and user experience.

The research evaluations focused on four main areas: the size and functionality of the product, the cognitive and emotional management of the operators, the perceptive aspects during the interaction with the device and the operators' skills. The collected data were used to develop a project proposal to improve the usability, safety, and effectiveness of the neonatal ventilator, which was done within a collaborative process that involved the research group in creating innovative solutions to optimise the service.

Phases 3-4: Data analysis and development of project concepts

The analysis and synthesis phase of the collected data allowed it to identify the critical issues and define the requirements for the system under examination. The data obtained from interviews, questionnaires and observations were organised and summarised in maps and diagrams to highlight the problem areas. The results of the questionnaires were represented in graphs that illustrate the response percentages to facilitate interpretation. Subsequently, in the development phase of the design concepts, the problems that emerged were addressed through the use of design-orienting scenarios (Manzini & Jégou, 2004), allowing the team to outline strategic visions for an innovative neonatal ventilator oriented to the needs of patients and operators in the context of the Neonatal Intensive Care Unit.

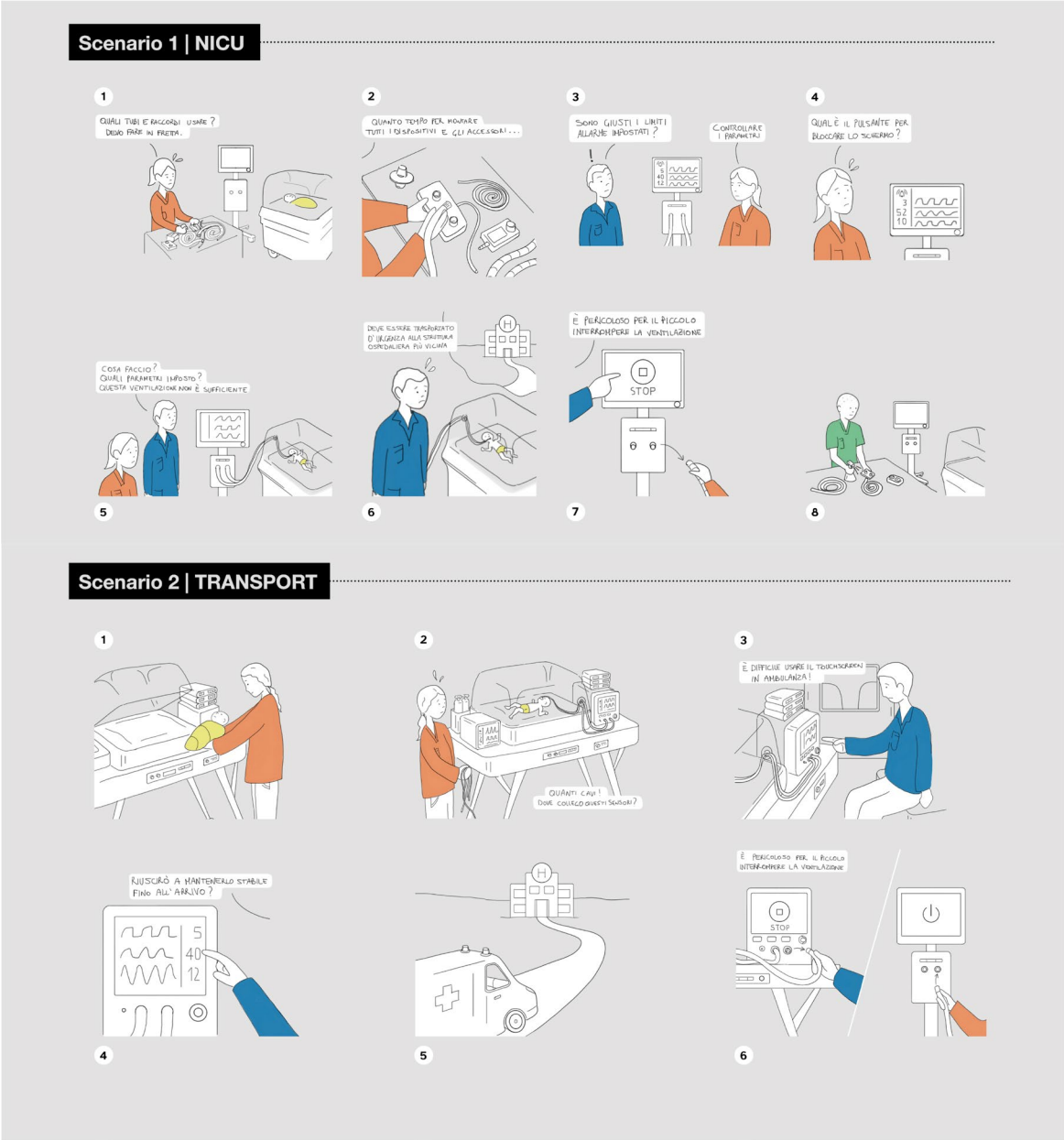

Figure 1. *Developing of two different scenarios: in-ward and during transport.*

Results

Evaluation and analysis of critical issues

The data analysis revealed several problems using neonatal ventilators in the ward and during transport. In the ward, the main critical

issues concern the difficulty assembling the components and switching between the different ventilation modes, problems such as alarm management, recognisability of the controls, and excessive condensation production by the humidifiers. Furthermore, possible errors were found during the assembly of the valve, as well as a lack of connections and non-shared updates.

The devices' weight, size, and complexity amplify the difficulties during transport, especially in emergency situations such as in an ambulance or helicopter. The touch screen is difficult to use in the ambulance, and the limited space in the vehicle makes it difficult to interact with the ventilator. Switching from ambulance gas to cradle gas is also difficult.

Further critical issues concern the arrangement and functionality of the connection ports, the usability of the graphic interface and the ventilation modes. In particular, the redundancy of connection ports, difficulty reading icons and graphs, and inefficiency in organising information emerged as obstacles. Problems were also found in using the humidifier and devices for ventilation with nitric oxide, with long assembly times and little practicality of use. Furthermore, the inability to detect dangerous environmental gases while using iNO (nitric oxide) was identified as a safety risk. Overall, the critical issues encountered in using neonatal ventilators mainly concern the assembly of the components, which varies according to the ventilation modes, and the difficulties related to the transportability of the device.

Furthermore, problems were highlighted in both the physical and digital interface, with difficulties viewing information and adjusting the necessary parameters. The presence of numerous additional devices during transport increases the complexity of use. Some actions (switching between ventilation modes or disconnecting the patient during transport) can be potentially dangerous. These issues, combined with the increased risk of operational errors, have led to low levels of user satisfaction. As a result, design solutions have been developed, in collaboration with industry experts, to improve the ventilator's reliability, safety and effectiveness.

Design solutions

The analysis of the critical issues that emerged from the study led to the development of a new generation lung ventilator called Andy, designed to simplify each phase of ventilatory assistance, reduce the risk of error and ensure continuous use without the need to discon-

nect the patient, both in the department and during transport. The project aimed to develop a single ventilator usable in different contexts, with simplified maintenance and an intuitive digital interface, and reduce the clutter of devices and cables. The main expected benefits included (see Fig. 2):

- For the workflow: reduced preparation times, ease of use and more significant order in workspaces.
- For the patient: continuity of ventilation even during transport, reducing the risk associated with disconnections.
- For the hospital structure: optimisation of resources and reducing maintenance and staff training costs.

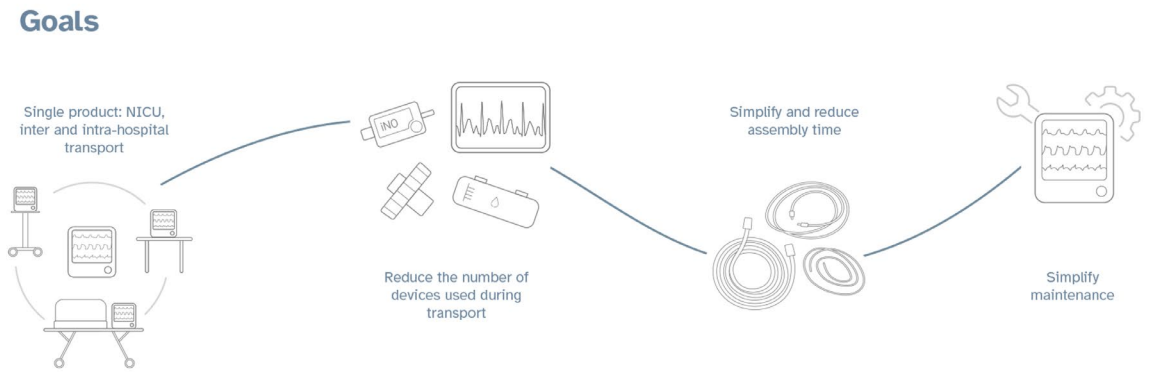

Figure 2. Main goals of Andy: ensure versatility in neonatal intensive care and transport, reduce device count, simplify assembly, enable seamless mode transitions without disconnections, and ease maintenance.

This integrated approach improves operational efficiency and quality of care, providing advantages for healthcare personnel and patients. The new lung ventilator has been designed considering three key concepts:

1. *Simplified morphology and physical interface*: The device integrates various devices, such as humidifiers and nitric oxide (iNo) delivery systems, to reduce the number of devices used and simplify ventilatory assistance, especially in emergencies or transport. This integration within the device simplifies the assembly of components and the monitoring of ventilatory parameters, eliminating the need for additional control devices. A small device, which can be positioned inside the incubator, collects the neces-

sary sensors, improving the organisation of cables and reducing the risk of connection errors thanks to easily recognisable ports and wireless technology (see Fig. 3).

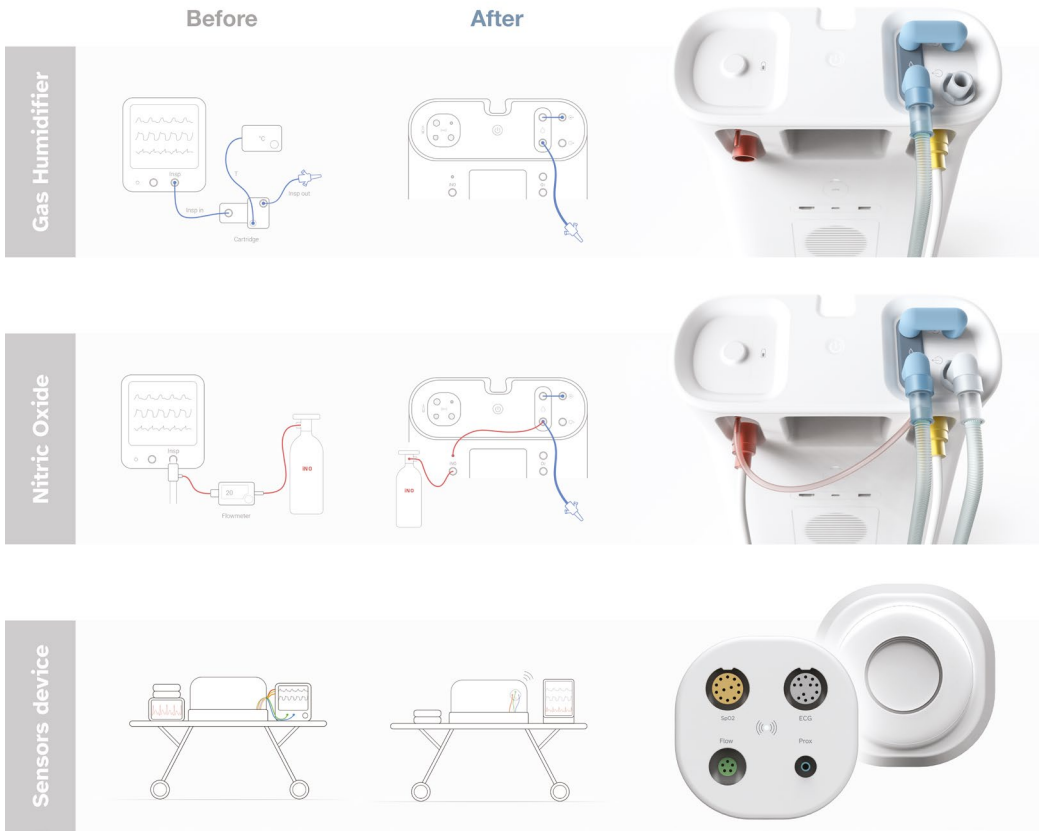

Figure 3. Morphology and physical interface of the new device: simplifying the care workflow and reducing the excessive number of devices used.

2. *Intuitive and simple digital interface*: A reclining and extractable tablet facilitates the control and modification of parameters, while a simple graphic interface, with clear icons and optimised visual contrast, reduces the cognitive load for healthcare professionals and speeds up medical operations. Furthermore, optimal colours and contrasts have been used to improve visibility and reduce visual stress. At the same time, the "neomorphic" graphic style visually distinguishes the selectable buttons through extruded elements that give the touch interface a physicality, at least visually, making the user experience more pleasant and tangible.

Furthermore, visual and sound feedback (yellow: low priority; red: high priority) helps to report any problems, reducing the risk of errors (see Fig. 4).

Figure 4. *Reclinable and removable tablet to facilitate the reading and adjustment of ventilation parameters (top) and digital interface of the new ventilator, which communicates detected issues to the user through visual and auditory feedback (bottom).*

3. *Versatility and portability*: Suitable for both the department and transport, the ventilator is compact, lightweight and made of high-performance biocompatible material with excellent mechanical resistance (Tecapro MT). An ergonomic handle and an anchoring base simplify fixing and handling, and a bag with dedicated compartments allows the ventilator to be transported together with all its components and accessories (see Fig. 5).

These improvements aim to optimise ventilatory assistance by reducing risks and simplifying the user experience for medical personnel.

Figure 5. Versatility and portability of the product.

Conclusions

The results of this study and Andy's design demonstrate the potential of human-centred design methodologies and ergonomics applied to the design to create safer and easier-to-use healthcare devices, improving the patient's care experience and the staff's workflow. Andy represents an evolution in neonatal ventilation, overcoming the limitations of current devices, which require disconnecting the patient when switching between different ventilators. This ventilator, designed for continuity and ease of use, reduces the risks associated with managing multiple interfaces and devices, ensuring more excellent safety for the neonate and smoother use for the healthcare staff. The recognition received from the iF DESIGN TALENT AWARD 2022 emphasises the importance of this innovation, highlighting how the combination of ergonomics and human-centred design has created a revolutionary solution for the medical sector. Andy represents a paradigm of innovation with the potential to change the approach to the

design of medical devices, with significant impacts both in neonatal care and in the training of healthcare professionals. With an intuitive interface and reduced number of devices required, training and maintenance time could be reduced, which would help optimise hospital resources. For the future, it is essential to create a prototype of Andy to implement a study capable of improving users' quality of life in a real context. Developing a prototype would open the possibility of direct user testing, allowing for real-world feedback and further refinement of the device. These tests would optimise practical and functional aspects and allow Andy to be adapted to a broader range of patients and clinical situations, thus expanding its applications beyond the neonatal context.

Furthermore, Andy provides an ideal basis for future technological evolutions, such as integrating artificial intelligence and remote monitoring systems, which could allow real-time adjustment and customisation of ventilator parameters based on patient conditions. This prospect paves the way for a generation of even more intelligent and integrated ventilators capable of adapting to the individual patient's needs and the healthcare context's different clinical needs. Andy, therefore, represents not only an answer to the current challenges of neonatal ventilation but also a promising starting point for future scenarios of medical ventilation that are more efficient, safe and centred on the needs of patients and operators (see Fig. 6).

Figure 5. *Andy - NICU Portable Ventilator.*

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Author Contributions

Conceptualization, E.I.; methodology, E.I. and A.C.; infographics, rendering and data curation, A.C; writing–original draft preparation, E.I.; writing–review and editing, E.I. (all sections except “Design Solution”) and A.C.; Supervision, E.I. and C.M. (technical part). All authors have read and agreed to the published version of the manuscript.

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