Applying Usability Engineering in Converged Design Process of Medical Device

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ABSTRACT IN ENGLISH

Applying Usability Engineering in Converged Design Process of Medical Device

Converged medical devices integrate multiple functionalities into a single system to enhance user convenience, optimize space efficiency, and improve treatment outcomes, all while reducing the burden on both patients and healthcare providers. As the demand for innovative medical solutions continues to grow, the importance of converged medical devices in advancing clinical efficiency, workflow optimization, and patient-centered care has become increasingly evident.

This study focuses on the design and development of a converged neonatal incubator that integrates an incubator, warmer, patient monitoring system, and phototherapy functions into a unified system. Usability engineering principles were systematically applied throughout the development process to ensure a user-centered and safe design. Seven iterative formative evaluations were conducted to refine the overall system design, while an additional eight formative evaluations focused specifically on enhancing the graphical user interface(GUI). A summative evaluation covering all core functionalities—incubator, warmer, patient monitoring system, and phototherapy—demonstrated an overall task success rate of 95.90%. Notably, patient monitoring and phototherapy tasks achieved a 100% success rate, while warmer-related tasks showed a success rate of 97.78%, validating the usability and effectiveness of the proposed medical device.

This study introduces a comprehensive design process for converged medical devices, which was developed and validated through the design of the neonatal incubator. The proposed process integrates four novel stages—User Needs Identification; Comparative, Functional and Risk Analysis; Iterative Design Process with Verification; and Medical Device Validation—within the existing frameworks outlined by ISO 13485 for medical device lifecycle management, IEC 62304 for software medical devices, and IEC 62366 for usability engineering. By adopting this systematic and iterative approach, this study demonstrates that usability, safety, and effectiveness of converged medical devices can be significantly enhanced. The findings provide a scalable and practical framework for the development of next-generation medical technologies, advancing the convergence of multifunctional systems to meet evolving clinical and patient needs.

Key words: Converged Medical Device, Design Process, Usability, Medical Device, Patient Monitor, Incubator, Warmer, Phototherapy

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1. INTRODUCTION

1.1 Background

1.1.1 Medical Device Design Processes

When designing medical devices, the U.S. FDA or ISO 13485:2016 mandates a development process that adheres to quality system requirements, such as quality system regulations, as illustrated in Figure 1[1]. In developing a new medical device, user requirements are first identified, followed by the design of the medical device to reflect these requirements. It is then assessed to ensure that each design output complies with the design input. After proceeding through the final verification stage, a completed medical device is created that is ready for market release. At this stage, it is validated to ensure that the final medical device meets user requirements[1].

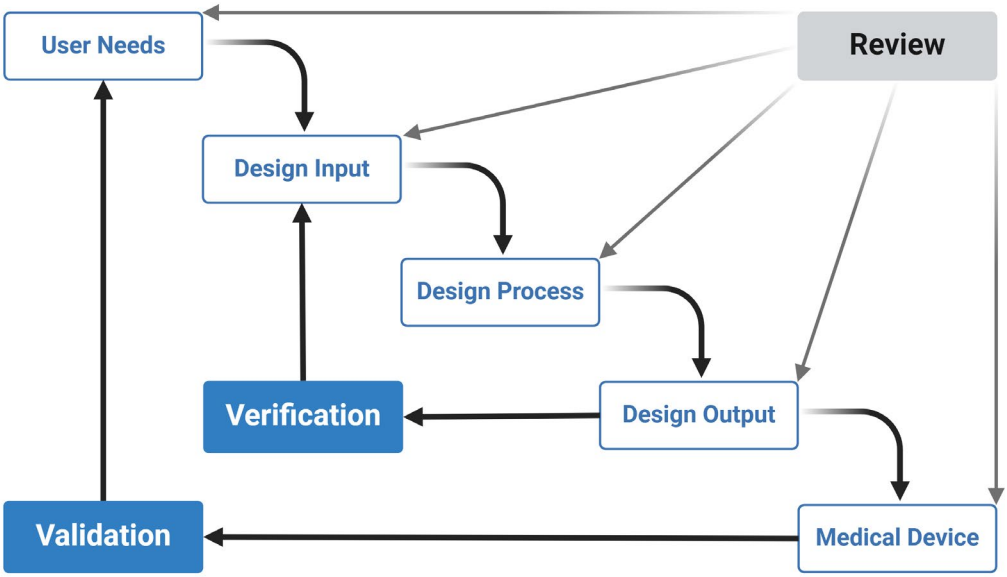


Figure 1. Application of Design Controls to Waterfall Design Process

Evaluating each step's completeness and checking for legal compliance are also essential. In particular, the verification stage entails using a prototype—the final output produced in the lab—to determine whether the result complies with the originally specified requirements. In this context, a prototype is an output created in a research setting in accordance with high-level specifications. By focusing on whether the final product—one that can be produced on the production line and sold in the market through design transfer—meets customer needs, validation, on the other hand, assesses client satisfaction rather than merely the end product in the lab.

It is crucial to consider risk management and usability throughout the entire development stage of a medical device. By leveraging user feedback, regulatory requirements, and technical information, companies can proactively identify and prevent potential risks associated with medical devices. Companies must independently assess potential risks and incorporate them into design inputs. The software medical device design process is applied specifically when developing software

embedded in electronic medical devices, aiming to enhance the quality and reliability of these software-based medical devices.

As illustrated in Figure 2, the V-model outlined in IEC 62304 presents the software development stages on the left and verification and validation (V&V) activities on the right[2,3]. The V&V model is an approach designed to fulfill the functional and non-functional requirements of medical device software, ensuring that safety and performance meet established standards. This model can be applied across all software development stages, playing a significant role in minimizing hazards that may arise throughout the life cycle. It includes requirements for verification, design verification, implementation verification, integration verification, system verification, and user verification.

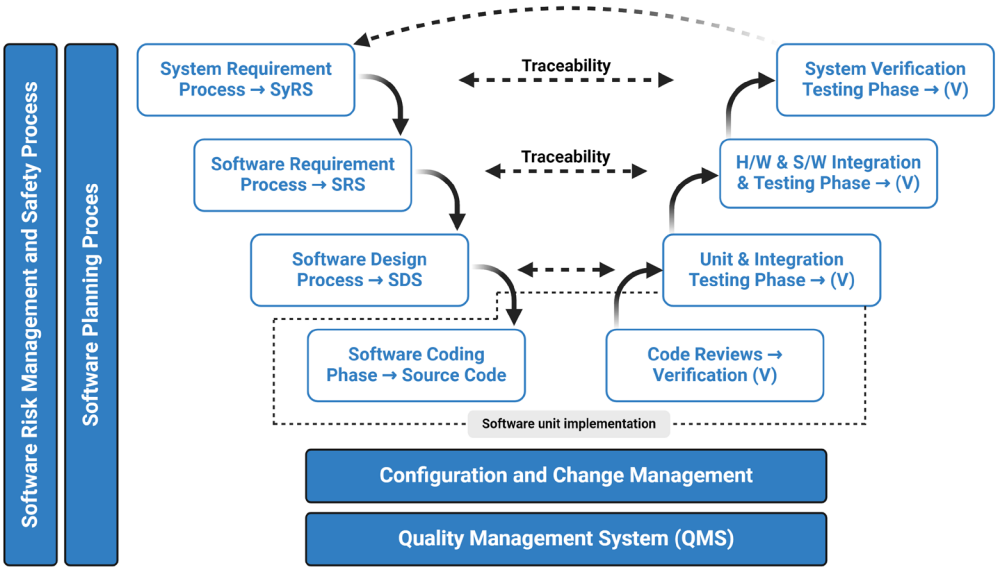
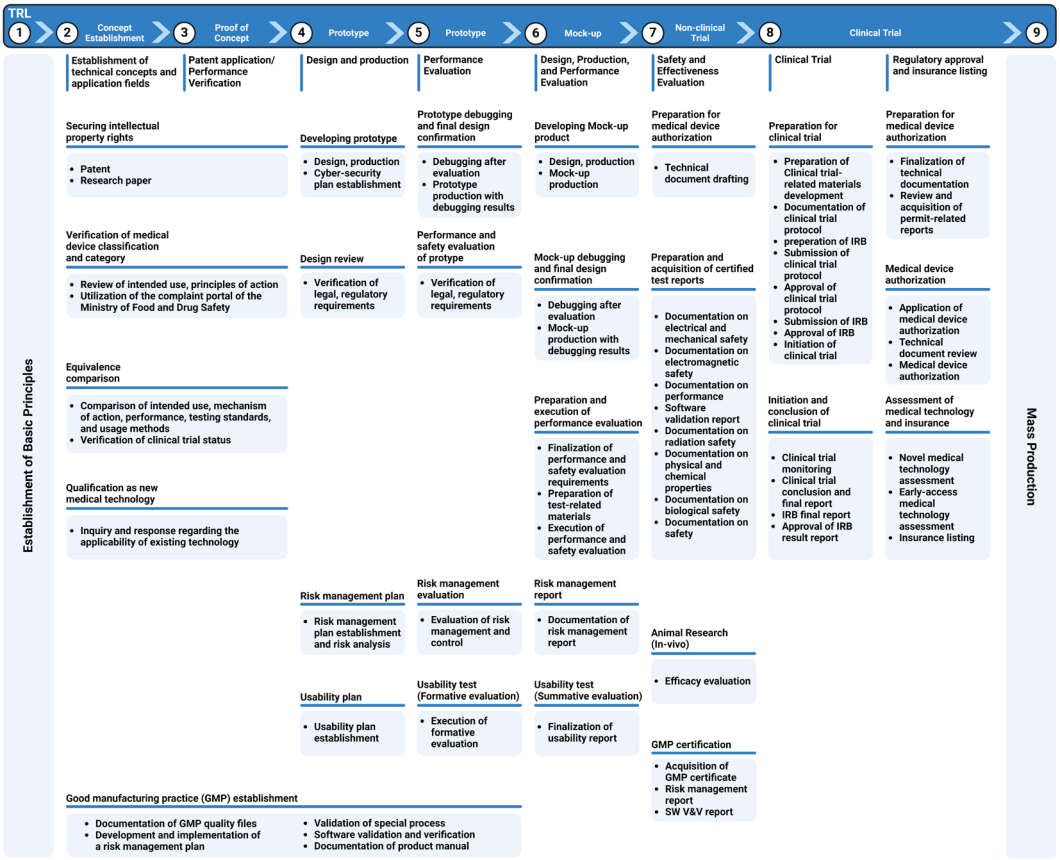


Figure 2. Software as Medical Device Design Processes

Standards related to quality management, device safety and performance, clinical effectiveness, common standards, and auxiliary standards—integral parts of the quality system required for developing a new medical device—must be applied to each respective item. Individual specifications and other factors must also be considered. Various standards are required, including ISO 13485, a quality management standard, ISO 14971, a risk management standard, and IEC 60601-1-6, which is related to usability. When developing a new device, it is important to recognize that the required standards are not isolated but interrelated; therefore, the device must be designed with these interconnected standards in mind throughout product development.

The Ministry of Food and Drug Safety, the Daegu-Gyeongbuk Advanced Medical Device Industry Promotion Foundation, the Osong Advanced Medical Industry Promotion Foundation, and the Pan-Ministry Lifecycle Medical Device Research and Development Industry Group have released the Medical Device Regulatory Science Milestone (ver. 2.0), which is depicted in Figure 3[4]. The regulatory data requirements that must be verified and prepared at every stage of research and development for final commercialization are highlighted in this description, which is divided into nine tiers depending on the technological readiness level (TRL) of electrical medical devices. Particularly in light of GMP, the significance of risk management and design modification during the TRL stages is underlined.

Medical device development begins with establishing a technical concept and application field, and after obtaining approval and insurance registration, mass production of the device is possible. Although different standards apply at each development stage, they are interconnected, requiring that devices be designed with consideration of all relevant standards. Notably, the usability process involves designing, manufacturing, and creating prototypes. When considering usability throughout the medical device's entire life cycle, it is essential to prioritize risk management standards, identify safety requirements, and investigate potential hazards.



Source : MFDS

Figure 3. Medical Device Regulatory Affairs Milestones

IEC 60601-1-6:2020, an auxiliary standard for usability, is now necessary as performance data specifically for electronic medical devices after its introduction by the Korean Ministry of Food and Drug Safety. Additionally, in accordance with the Medical Device Manufacturing and Quality Control Standards (Ministry of Food and Drug Safety Notification No. 2019-25), the international GMP standard ISO 13485:2016 was adopted starting in July 2022, requiring GMP audits for all medical device classes[5].

Even before domestic legislation required the production of usability documentation for medical devices, United States emphasized the importance of usability. United States is the largest medical device market in the world which accounts for about 38% of the global medical devices market[6]. The importance of usability is emphasized in the FDA's 2016 guidance, Applying Human Factors and Usability Engineering to Medical Devices. Furthermore, submission data is categorized using a risk-based methodology in the 2022 draft advice on the Content of Human Factors Information in Medical Devices Marketing Submissions. This latest guidance particularly focuses on a risk-based approach by adjusting the required documentation for license submissions based on the critical tasks within the user interface that are present or could change within the device[7].

Additionally, with the growing importance of usability, there is a focus on identifying known or foreseeable hazards and hazardous situations to analyze use errors and improve usability in existing devices. The FDA's MAUDE (Manufacturer and User Facility Device Experience) database emphasizes incorporating usability improvements by reviewing post-market surveillance (PMS) data[7, 8]. Furthermore, an analysis of the Medical Device Adverse Event Reporting System (MAUDE) data provided by the U.S. FDA from 2010 to 2018 revealed that 28.1% of reports containing device problem codes were attributed to use errors[9].

However, in Korea, rather than reviewing usability-related data during the medical device licensing stage, as done in the United States, relevant documents are primarily reviewed during the GMP review process. Since the introduction of ISO 13485:2016, manufacturers face significant challenges in assessing usability, often needing to conduct usability assessments again to gain approval in international markets. For domestic manufacturers, it is common for device designs to proceed without sufficient usability evaluation and improvement processes throughout the entire medical device lifecycle[10].

If the usability engineering process is not integrated and applied during the design phase, newly developed medical devices may be challenging to learn and difficult to use. For detailed information on usability, please refer to IEC 62366. According to IEC 62366-1, the usability engineering process for medical devices is divided into four stages: User Research, Analysis, Design and Formative Evaluation, and Summative Evaluation[11, 12].

1) User Research

User research is conducted early in the medical device development process and is crucial for identifying the various user groups that will interact with the device. It is essential to consider the intended user and the intended use environment of the device being developed. At this stage, use specifications are prepared, including medical indications (purpose of use), intended user, site of action, intended user profile, intended use environment, and the operating principles of the medical device.

2) Analysis

This step involves identifying safety-related user interface characteristics and potential use errors. By examining adverse events and side effects observed in devices similar to the one under development, hazards and hazardous situations can be identified. Additionally, use errors can be recognized by analyzing the requirements of the intended users.

3) Design and Formative Evaluation

This stage involves developing a design based on the analysis phase, implementing the design, and then conducting formative evaluations. Formative evaluations must be carried out from the early stages of device development to identify use errors and make necessary adjustments to the device's user interface. This evaluation is conducted before the summative evaluation, with the number of participants varying based on the evaluation method; however, usability evaluation is typically performed with 5 to 8 participants as recommended by IEC 62366-2. Table 1 below lists the justifications for evaluating with five to eight individuals[12]. If use problems occur more than 25% of the time, usability issues can be discovered in 76% of cases with 5 participants and 90% of cases with 8 participants, according to IEC 62366-2:2016 Annex K, which examines the chance of discovering usability issues based on the number of participants[12].

Table 1. Cumulative Probability of Detecting a Usability Problem[12]

Usability Defect Probability of Occurrence	**Number of Test Participants**													
	1	**2**	**3**	**5**	**6**	**7**	**8**	**10**	**15**	**20**	**25**	**50**	**75**	**100**
1.0	1	2	3	5	6	7	8	10	14	18	22	39	53	63
3.0	3	6	9	14	17	19	22	26	37	46	53	78	90	95
5.0	5	10	14	23	26	30	34	40	54	64	72	92	98	99
10	10	19	27	41	47	52	57	65	79	88	93	99	100	100
15	15	28	39	56	62	68	73	80	91	96	98	100	100	100
25	25	44	58	76	82	87	90	94	99	100	100	100	100	100
50	50	75	88	97	98	99	100	100	100	100	100	100	100	100
75	75	94	98	100	100	100	100	100	100	100	100	100	100	100
90	90	99	100	100	100	100	100	100	100	100	100	100	100	100

4) Summative Evaluation

This is the stage to verify whether the final designed device can be safely used in a real-use context. If the risk of use errors identified in the previous step is not effectively controlled as a result of the summative evaluation, a formative evaluation must be conducted again. According to IEC 62366-1, at least 15 members from the intended user group should participate in the summative evaluation[12]. For the reason behind evaluating with over 15 people, please see Table 1[12]. As shown in Table 1, using 15 participants is effective in identifying 99% of usability issues and detecting potential problems[12].

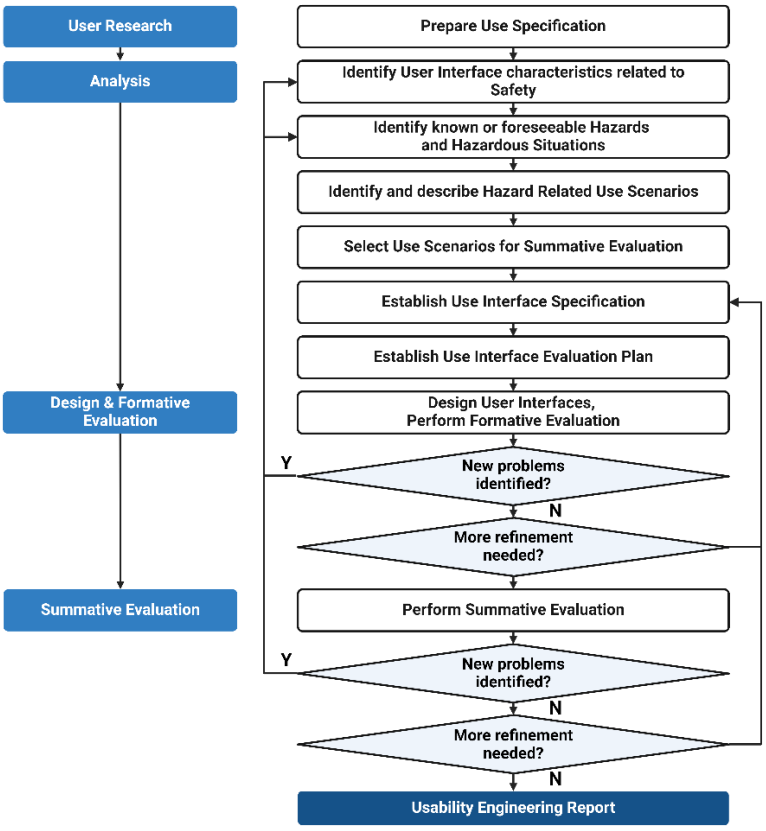


Figure 4. Usability Engineering Process

We investigated the key considerations for designing medical devices through the medical device system design process, the software medical device design process, and usability-related processes. It is crucial to include specific requirements during the design phase, develop designs based on these requirements, conduct formative and summative evaluations, and incorporate insights derived from predictable risks into the design during the development process. Additionally, this approach aligns with standards where usability and risk management are interrelated. Risk factors identified through risk management are analyzed and integrated into the usability engineering process, allowing for the development of medical devices with enhanced usability by systematically addressing these risk factors.

Therefore, when designing medical devices, product realization and risk management procedures must be integrated and implemented as shown in Figure 5, and a systematic engineering process must be carried out.

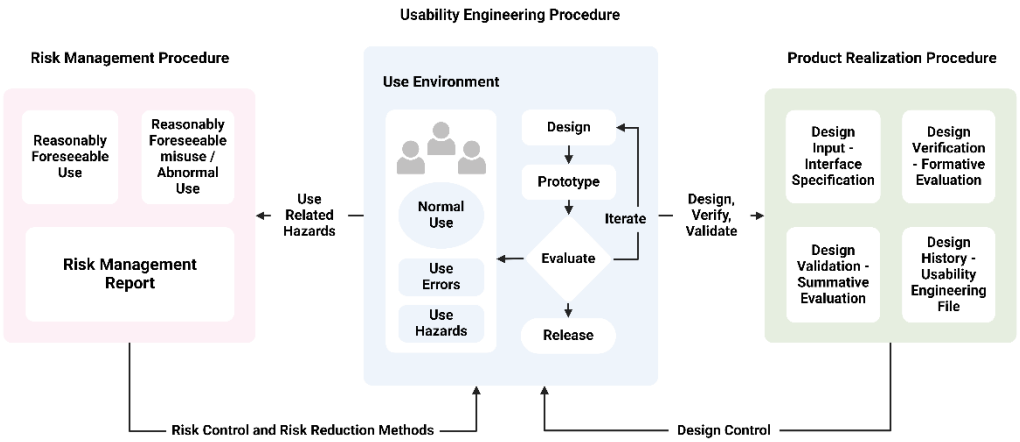


Figure 5. Usability Regulations for Medical Device Design

1.1.2 Converged Medical Device

1) General Converged Medical Device

According to this study, a "Converged Medical Device" is a single medical device that incorporates several different kinds of functionalities, as shown in Figure 6. Converged medical devices provide the benefit of combining various technologies to lessen the burden of medical staff and enhance patient results. The advancement of medical technologies and the growing complexity of healthcare challenges have driven the need for innovative solutions that enhance patient care while addressing efficiency and cost-effectiveness. Among such innovations, converged medical devices have emerged as a transformative approach in modern healthcare. These devices integrate multiple functions, technologies, and disciplines into a single system, aiming to improve usability, streamline workflows, and optimize clinical outcomes.

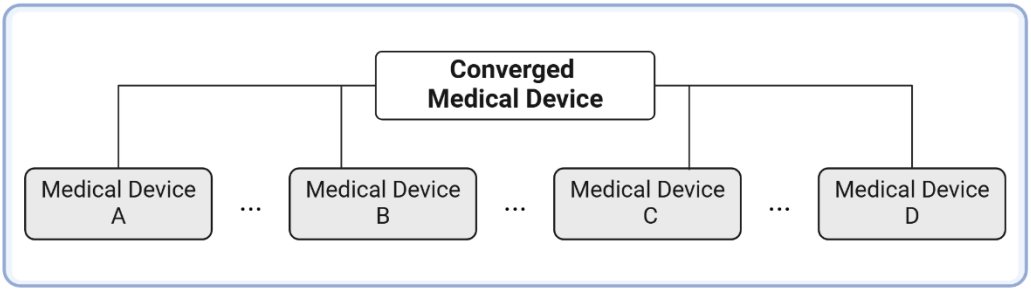


Figure 6. Converged Medical Device

A converged medical device is characterized by its ability to combine various medical functions, such as monitoring, treatment, diagnosis, and communication, into one platform. In addition to eliminating the need for numerous separate devices, this integration improves data interoperability, conserves space and decreases maintenance expenses. For instance, a device that simultaneously

monitors vital signs, provides therapeutic support, and connects to electronic medical records exemplifies the potential of convergence in improving care delivery.

This is very beneficial in settings with limited space, such as intensive care units, neonatal intensive care units, or emergency departments, where space efficiency is crucial. Inefficiencies, elevated infection risks, and additional workloads for medical personnel can result from this disjointed arrangement. Converged medical devices offer a chance to revolutionize patient care by combining these features into a single, integrated system. They lower the dangers connected with many device interfaces and disorganized data flows, which not only makes equipment management easier but also enhances patient safety. Furthermore, fewer devices may now be operated by healthcare staff, which simplifies procedures and reduces the need for training. Devices that integrate multiple functions can assist medical staff in navigating complex medical environments, enable rapid clinical decision-making, and facilitate swift improvements in the patient's condition.

Particularly in Korea, innovative medical devices that combine many functions are being developed. Examples include devices that combine x-ray and ultrasound, artificial intelligence, and the Internet of Things. To position Korea as a leader in medical technology, the government has prioritized the development of converged medical devices. Policies and investments focus on meeting global demand by emphasizing innovation and export potential.

2) Converged Neonatal Incubator

This study explains the design and development process of a "Converged Neonatal Incubator" as a working model of "Converged Medical Device." We aim to investigate the background of the incubator, which serves as the primary function of converged medical devices.

A neonatal incubator is a medical device primarily used to maintain the body temperature and physiological stability of premature infants[13, 14]. Under Korean regulations on medical device categories and product classifications, incubators are classified as A10000 devices. As shown in Table 2, subcategories are divided into stationary incubators, portable incubators, and mobile incubators. Both domestic and international incubators play a crucial role in supporting the survival and health of newborns by controlling temperature, humidity, oxygen levels, and other factors to improve the medical environment for neonates[14].

Table 2. Overview of Incubator Items in MFDS

Classification No.	Product Item Name	Class	Definition
A10010.01	Incubator, infant	3	• A sturdy, box-shaped device designed to improve the medical environment for newborns. It includes a power heater, an air purification fan, a water tank for humidity control, and, in some models, an oxygen connection port
A10020.01	Incubator, infant, transportable	3	• A sturdy, box-shaped device used to improve the medical environment for newborns during transportation
A10020.02	Incubator, infant, mobile	3	• A sturdy, box-shaped device with wheels for mobility, used to improve the medical environment for newborns during transportation

The U.S. FDA has product codes FMZ and FPL, as shown in Table 3, and like in Korea, the United States categorizes incubators into stationary incubators and transportable incubators. In the

US, domestic transportable incubators and mobile incubators are classified under the FPL code. Additionally, these are Class 3 products in Korea, while they are classified as Class II medical devices in the United States.

Table 3. Overview of Incubator Items in FDA

Device	Product code	Device class
Incubator, neonatal	FMZ	II
Incubator, neonatal transport	FPL	II

Incubator, heater, pediatric phototherapy units, neonatal patient monitoring systems, and ventilators are among the medical device utilized in the NICU[15-17]. Table 4 shows the classes and definitions of medical devices used in the NICU.

Table 4. Medical Devices Used in NICU(Neonatal Intensive Care Unit)

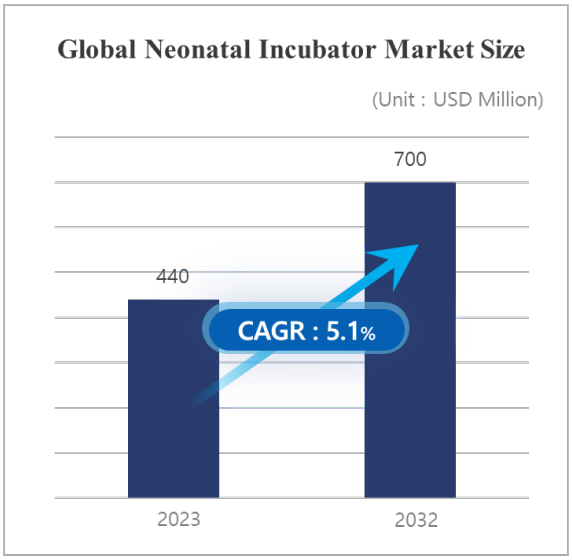
Classification No.	Product Item Name	Class	Definition
A10030.01	Heater, infant	2	• A device that uses a heat source to maintain the infant's body temperature
A16030.01	Pediatric phototherapy unit	2	• A device that emits a specific wavelength to treat or prevent jaundice in newborns
A26090.0	Patient monitor	2	• A device that monitors various biometric data of the patient and generates a visual or auditory alert in case of risk
A26090.02	Patient monitoring system, transportable	2	• A device that monitors various biometric data of patients and consists of a specific combination of modules for invasive blood pressure, electroencephalogram, and carbon dioxide measurement. An alarm is generated visually or audibly in case of risk

Classification No.	Product Item Name	Class	Definition
A26090.05	Patient monitoring system, neonatal	2	• A device that monitors various biological information of newborns
A07010.0	Ventilator, neonatal/pediatric	3	• A device that provides breathing gas containing a specific amount of oxygen to support long-term respiration for newborns and pediatric patients with variable respiratory needs. It supplies, assists, or regulates breathing

The incubator was developed by a French obstetrician who sought a way to warm newborns dying from hypothermia[18]. Inspired by poultry incubators, it was first used in the United States in the 1890s and was developed to maintain body temperature in newborns[19, 20]. The development of these incubators reduced the mortality rate of premature infants[19]. Since 1898, incubators have seen user interface improvements with the addition of warmer, air circulation, and humidity control functions[13, 19].

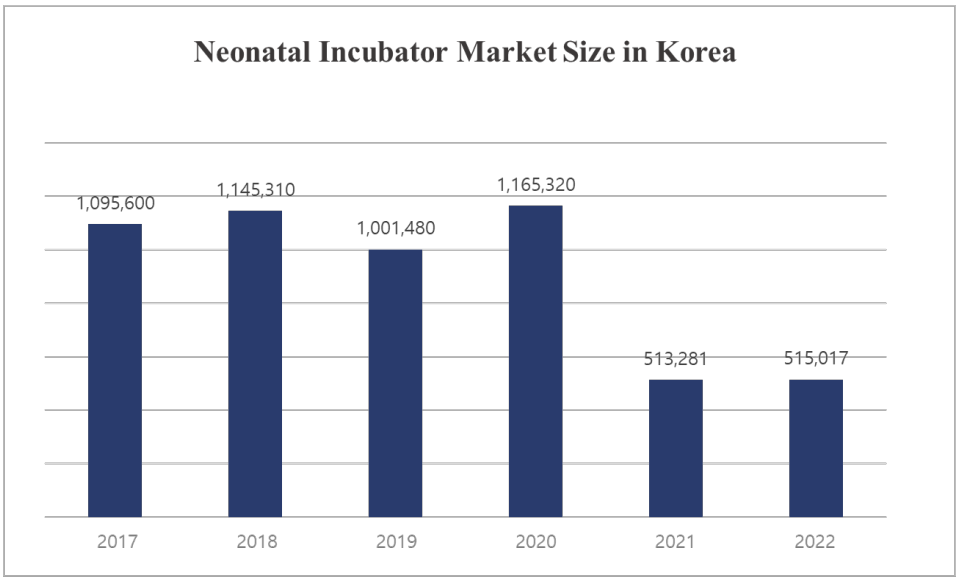
However, over the past 30 years, although there have been some user interface improvements, such as lighting, noise reduction, and ease of cleaning, there has not been a significant overall change[21]. This highlights the need for continued development of the incubator's user interface, particularly for a new design that can enhance both patient safety and user experience.

An incubator is a device that helps infants grow and develop in a regulated setting, much like a mother's womb[19]. As such, it can be considered a necessary medical device that needs to be managed by a physician[22]. Users of the incubator include the parents of the infants admitted to the NICU, the NICU medical team who run the machine, and the infants who are cared for and grow within the incubator. Compared to other medical devices, safety and usability are critical since real patients are inside the incubator, undergoing procedures during treatment and using it for a variety of therapeutic objectives.



Source : Newborn Incubator Market Research Report 2032(DATA INTELO)

Figure 7. Global Neonatal Incubator Market Size



Source : KHIDI

Figure 8. Neonatal Incubator Market Size in Korea

The global neonatal incubator market is anticipated to expand at a compound annual growth rate (CAGR) of 5.1%, from USD 440 million in 2023 to over USD 700 million by 2032, as illustrated in Figure 7[23]. The frequency of illnesses among infants and premature infants is the main factor driving this market expansion. Because of large investments in cutting-edge medical care as well as research & development, North America dominates the neonatal incubator industry regionally. Furthermore, during the projection period, the Asia-Pacific region is anticipated to have the fastest growth rate[23].

As shown in Figure 8, the domestic incubator market grew from KRW 1,095.6 million in 2017 to KRW 1,165.32 million in 2020[24]. However, COVID-19 caused a higher focus on developing products like ventilators and genetic testing reagents for high-risk infectious agents, rather than incubator-related things, which is why the incubator market declined from 2020 to 2021.

As of 2023, Domestic medical institutions rely on imported incubators, with 79.1% of total incubator use dependent on foreign devices. Consequently, foreign devices are predominantly used in domestic NICU. To promote the commercialization of domestic medical devices, it is essential to develop a converged incubator for treating premature infants that combines an incubator, a warming device, a patient monitor, and a phototherapy device into a single device.

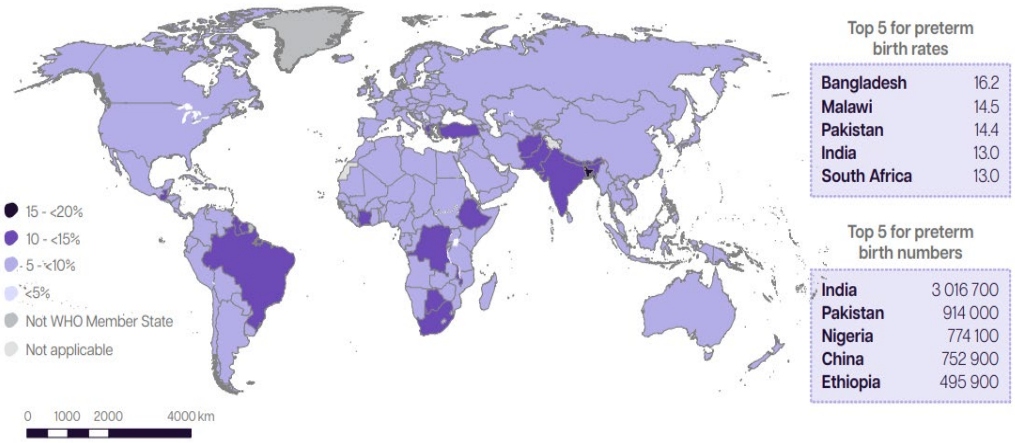
Preterm infants are defined by the WHO as those born before 37 weeks of pregnancy, and they are divided into three subgroups according to gestational age. Extremely preterm infants are those born before 28 weeks, very preterm infants are those born between 28 and 32 weeks, and moderately to late preterm infants are those born between 32 and 37 weeks[25, 26]. According to Korea's Maternal and Child Health Act, infants delivered before 37 weeks of pregnancy or with a low birth weight—that is, weighing less than 2,500 grams—are considered preterm[27]. The patient population utilizing incubators is comprised of low birth weight and premature infants, as indicated in Table 5, where definitions and classifications are given for each term[28].

Table 5. Comparison of Definitions: Low Birth Weight Infants vs. Premature Infants

Category	Preterm Infants	Low Birth Weight Infants
Primary Definition	• (WHO) Infants born before 37 weeks of pregnancy • (KOREA) Infants born before 37 weeks of pregnancy or infants weighing less than 2,500 grams at birth	• (WHO) Infants weigh less than 2,500 grams at birth
Sub-classifications	• Extremely preterm (less than 28 weeks) • Very preterm (28 to less than 32 weeks) • Moderate to late preterm (32 to 37weeks)	• Very Low Birth Weight (VLBW): < 1,500 grams • Extremely Low Birth Weight (ELBW): < 1,000 grams
Overlap	• All premature infants born before 37 weeks are categorized under this definition	• Preterm infants are often also low birth weight, but not all low-birth-weight infants are preterm

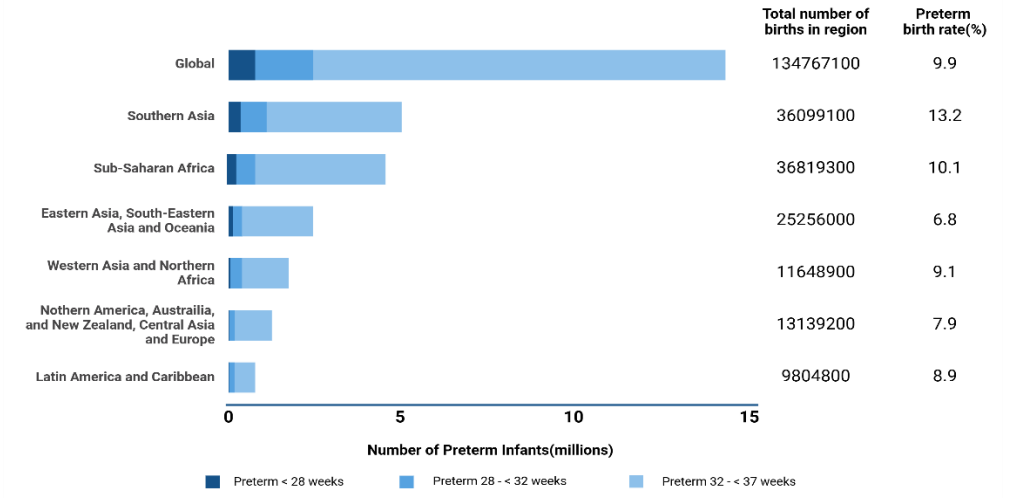
Around 13.4 million infants were born prematurely globally as of 2020, making up around 10% of all births[28]. At 9.8%, the worldwide preterm birth rate was marginally lower in 2010. The global rate of preterm births in 2020 is displayed in Figure 9. Premature birth can happen when a woman goes into spontaneous preterm labor or when an infection or other pregnancy issues necessitate an early labor induction or cesarean section. Despite the fact that preterm deliveries occur all around the world, more than 90% of extremely premature infants in low-income nations pass away within a few days after birth because they lack the necessary medical supplies and care. On the other hand, this mortality rate is drastically lowered to less than 10% in high-income nations.

In particular, it can be observed that the premature birth rate is higher in South Asia and Africa than in other regions, at 13.2% and 10.1%, respectively[28].



Source : WHO and UNICEF preterm estimates

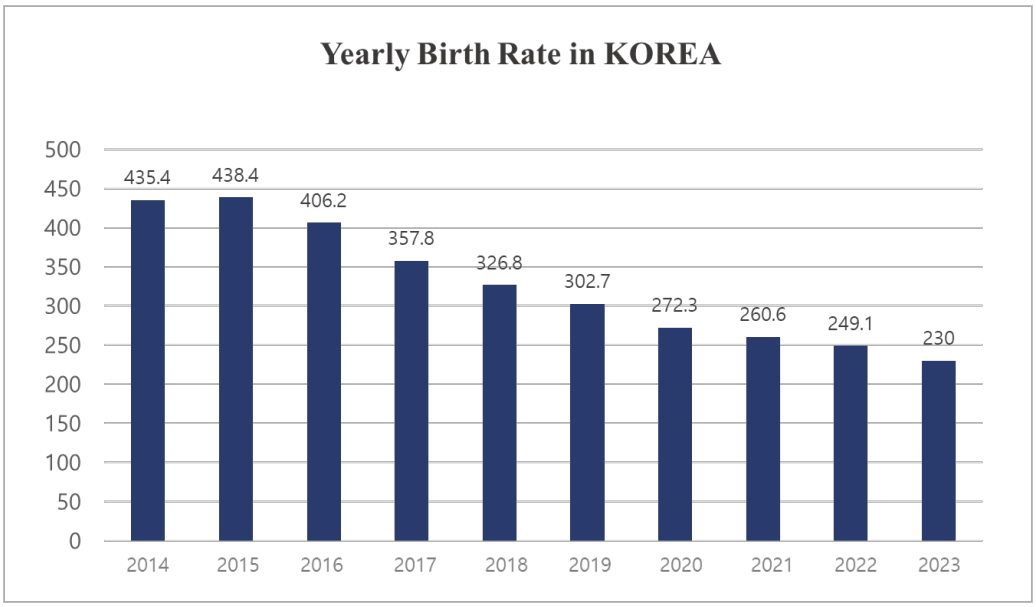
Figure 9. Estimated National Preterm Birth Rates and Numbers in 2020



Source : WHO and UNICEF preterm estimates

Figure 10. Preterm Birth by Gestational Age and Region in 2020

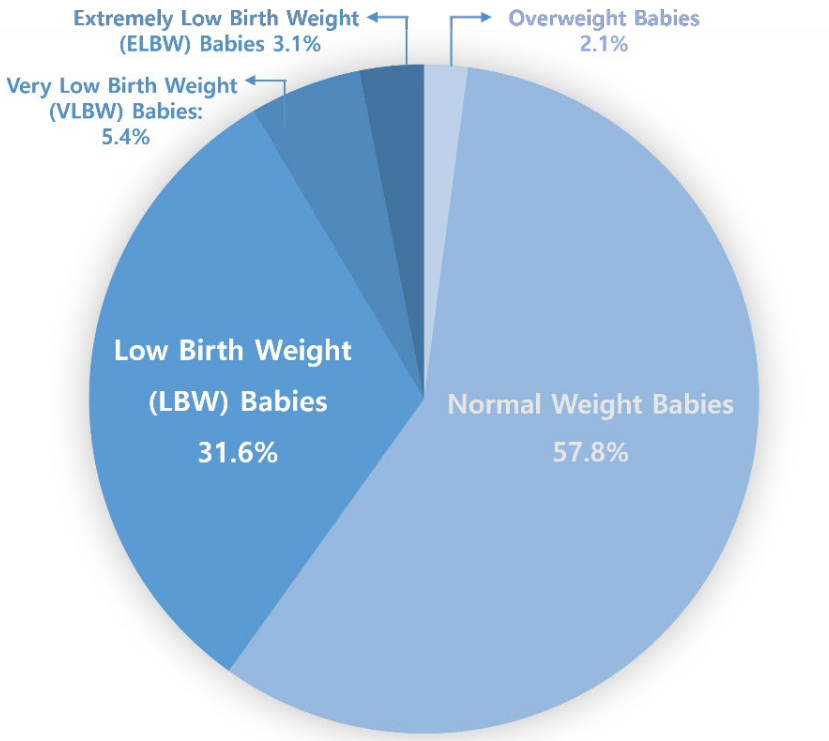
According to Figure 11, there were 230,028 births in Korea in 2023 as opposed to 249,186 in 2022, a 7.68% drop. However, as mothers age and the use of artificial insemination increases, the number of premature infants keeps rising. The incidence of high-risk infants, such as multiple births and premature infants, is rising in tandem with the sharp rise in artificial insemination use. Specifically, the percentage of newborns born before 37 weeks is 9.7%, which is 2.0 percentage points more than in 2018[29, 30]. Although treatment technology and equipment for critically ill newborns are advancing, 53.1% of infant deaths in Korea occur among newborns less than 28 days old. Therefore, a patient safety-centered management system needs to be strengthened and the treatment environment in neonatal critical care units needs to be improved.



Source : KOSIS

Figure 11. Yearly Birth Rate in Korea

According to the findings of the Health Insurance Review and Assessment Service's third evaluation of the adequacy of neonatal intensive care units in 2022, 40.1% of infants in NICUs were underweight (weighing less than 2,500g), 57.8% were normal weight (weighing between 2,500g and less than 4,000g), and 2.1% were overweight (weighing more than 4,000g) at birth. Low birth weight infants comprised of 31.6% of infants weighing between 1,500g and less than 2,500g; 5.4% of infants weighing between 1,000g and less than 1,500g; 2.9% of infants weighing between 500g and less than 1,000g; and 0.2% of infants weighing less than 500g[29].



Source : HIRA

Figure 12. Birth Weight Distribution Status

As the incidence of preterm births and low birth weight infants rises despite declining birth rates, continued development of neonatal care equipment is essential to provide better support and improved outcomes for these vulnerable groups. Although birth rates are decreasing globally, low-income countries have higher birth rates than high-income countries, along with a significantly higher number of premature infants. For companies targeting low-income countries, price competitiveness is crucial, as cost issues often prevent access to appropriate treatment.

Due to the nature of NICUs, various equipment is required to treat patients. In low-income countries, the cost of purchasing and maintaining each device can be high, presenting a financial burden. In contrast, in high-income countries, where incubators and medical devices are well-developed, space efficiency and usability are prioritized. There is a tendency in these countries to place greater emphasis on product performance and quality rather than price competitiveness.

While the need for incubators is high in all countries, numerous accidents have occurred during their use. In July 2013, in China, a 12-day-old newborn suffered full-body burns and died due to hospital staff mismanaging an incubator[31, 32]. The temperature had been set too high overnight, resulting in severe burns on the infant's back and legs[31]. In September 2015, an accident in a hospital in Belize, Central America, involved a rat entering an incubator and biting a premature infant less than a day old[31]. Additionally, from April to September 2017, 241 newborns died in India due to insufficient numbers and malfunctioning of incubators. In August 2017, around 30 newborns died in one month in India because incubators lacked sufficient oxygen[31]. In Korea, a 2017 incident involved the deaths of four newborns from infections in a hospital[31, 32]. Because of the nature of NICUs, it has been verified that medical mishaps resulting in sepsis have happened because of problems like burns and infections in incubators, which are commonly used to keep newborns' bodies warm.

According to Figure 11, the first thing to do after an infant is born is to evaluate its health in the delivery room using a variety of medical devices to look for any anomalies. Newborns typically have poor respiratory and temperature regulating skills right after delivery, therefore a warming device is utilized to assist in stabilization. A warming device is crucial in rapidly stabilizing the newborn's physiological state since it offers heat to prevent hypothermia and maintain body temperature.

The newborn is transferred to a mobile incubator and then taken to the NICU after their breathing, heart rate, and body temperature have stabilized. Using an integrated monitoring system, the mobile incubator allows for continuous monitoring of the newborn's condition while maintaining body temperature and facilitating oxygen delivery throughout transportation. Newborns are placed in an incubator after being moved to a warming device to regulate body temperature upon arrival at NICU. In addition to incubators, the NICU uses a variety of medical devices to keep an eye on the newborn's health. Usually, a patient monitoring system is utilized to track the newborn's biometric data, and medical personnel act quickly to address any unusual symptoms.

In addition, phototherapy is administered separately for premature and low-birth-weight infants, where light is used on newborns with jaundice to lower blood bilirubin levels and help them recover to a safe state. Therefore, at least four types of medical equipment are needed in the NICU to treat premature infants: incubators, patient monitoring systems, phototherapy, and, when necessary, ventilators are also used. As such, multiple medical devices occupy space while serving different functions, and if the interconnection between each device is not seamless, treatment time may be delayed.

The conventional method of employing several different medical devices is expensive and necessitates that medical personnel configure each device independently, which increases management complexity. Additionally, inefficient use of the restricted NICU area may result from

the spatial separation of devices. Significant problems with the NICU's current procedures include inefficient use of space, more expenses for buying, setting up, and maintaining every piece of device, more work for the medical personnel, and a decreased ability to respond to emergencies. To address these challenges, it is essential to develop a converged neonatal incubator as illustrated in Figure 13.

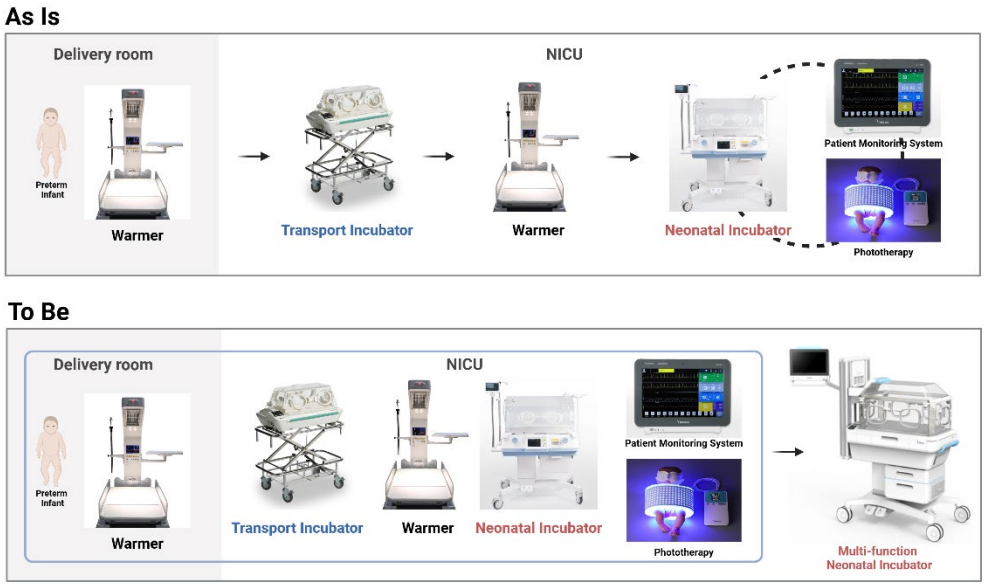


Figure 13. Neonatal Incubator Operation and Use Process

Additionally, the COVID-19 pandemic has raised awareness of risks caused by hospital-acquired illnesses. Because their immune systems are still developing, premature infants are particularly vulnerable to infections and are considered a high-risk population for illnesses. Instead of being placed in a warming device and then moved to an incubator, premature infants are safer when they are sent straight to the NICU through a converged incubator after birth, where they can get treatment. Short stays in conventional incubators may be sufficient for full-term newborns, but premature neonates need real-time heart rate, breathing, and oxygen saturation monitoring in addition to temperature control and infection prevention.

Preterm infants require higher safety standards because they are more susceptible to complications and are more sensitive to environmental factors than adults. Given that preterm newborns, not adults, are treated with these devices, it is crucial to consider the patient's size and customize the space to meet their unique requirements. In order to encourage growth and neural development, medical devices for infants must also support developmental care by simulating a womb.

A thorough grasp of neonatal physiology and a strong emphasis on safety and developmental needs are necessary for the creation of these devices. An iterative design approach including NICU medical professionals is essential when creating such medical devices in order to take into consideration the unique characteristics of the patient who will be using the device. Furthermore, strict specifications are required in order to fulfill all safety regulations and provide this high-risk group with dependable treatment.

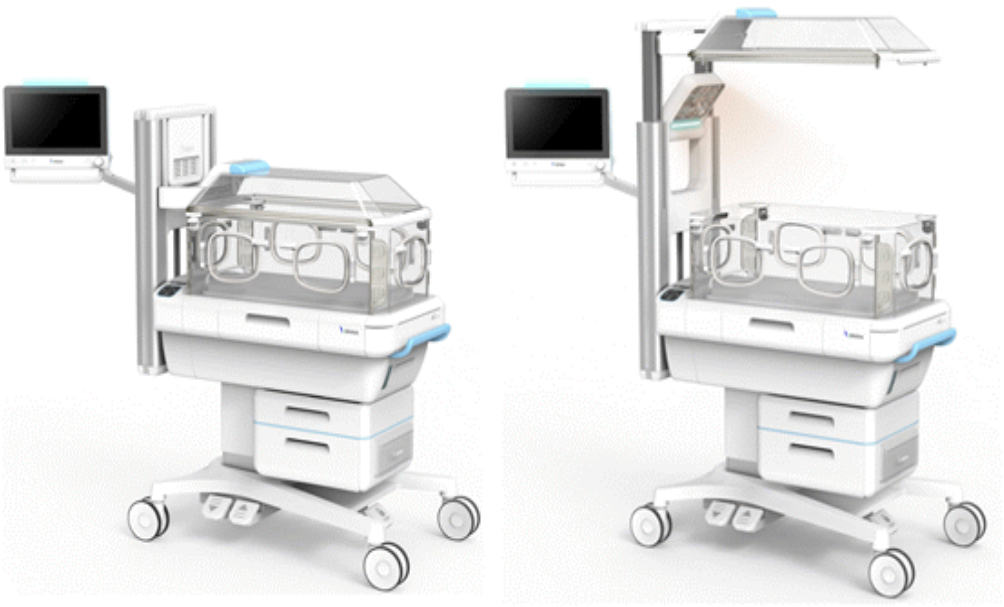


Figure 14. Converged Medical Device: Incubator, Warmer, Patient Monitoring System

1.2 Purpose

In contrast to conventional single-function medical devices, this study attempts to suggest a converged design process for creating a converged medical device that improves usability and efficiency by merging several functions. It also aims to outline certain techniques for integrating usability into the converged medical device design process. The increasing need for medical devices that combine multiple tasks to increase efficiency and usability makes it imperative to think about a method that puts usability and clear design first. In this study, we aim to outline the design process for converged medical devices by developing a converged neonatal incubator. By proposing a converged medical device design process, this study aims to emphasize simplified workflows and increased efficiency for users of such devices, while also enhancing space utilization. By applying the design process from the early stages, we also seek to assist medical device manufacturers in developing products that meet user needs.

Through the converged neonatal incubator design process, this study aim to develop a neonatal incubator that integrates multiple functions, primarily for use with preterm infants in NICU. The device combines an existing incubator with a warmer, phototherapy, and a patient monitoring system. The incubator display and patient monitoring display are integrated into a single interface within the incubator, allowing the patient's bio-signal, weight, and humidity to be monitored directly within the incubator. Introducing a convergence-type neonatal incubator can streamline the treatment process in the NICU and enable quicker responses, thereby enhancing overall treatment outcomes. Additionally, by conserving space, lowering maintenance expenses, and assisting in lowering the risk of infection for susceptible infants, this discovery aims to optimize the NICU environment. It is anticipated that the converged medical devices would increase in the NICU setting in the future, greatly enhancing the efficacy of life support and treatment for preterm infants.

1.3 Method

1.3.1 Converged Medical Device Design and Usability Engineering Activities

In this study, a converged incubator device is developed using a design process. The focus is to integrate existing incubators with warmers, phototherapy, and patient monitoring systems. Following the 'Converged Medical Device Design Process' for developing a converged neonatal incubator, the study encompasses activities such as identifying user requirements, conducting analyses, implementing the design process with verification, and performing medical device validation.

For graphical user interfaces (GUI) on the software side, we examined, designed, and developed the user interfaces and GUI of incubators and patient monitoring systems using Adobe XD, a prototyping tool. For incubators, we improved the GUI of GE Healthcare, Drager, Atom, and Bistos, while for patient monitoring systems, we created an integrated GUI by enhancing the GUI of GE Healthcare, Drager, Philips, and Bistos. The final GUI integrated each screen so that the patient's biometric information is viewed on one screen, displaying only the parameters that can be monitored within the incubator. The design underwent revisions and improvements based on usability evaluations of the developed user interface and GUI.

1.3.2 Suggestions of Converged Medical Devices Design Process

To specify the application of usability within the design process when developing a converged medical device, we referred to the medical device life cycle process, medical device software life cycle process, IEC 62366 (a usability-related standard), FDA guidance, and Ministry of Food and Drug Safety guidelines. Therefore, we developed the "Converged Medical Devices Design Process"

by integrating the medical device usability engineering process with the existing design processes for medical and software-based medical devices.

By focusing on usability evaluation and the design and improvement of user interfaces and graphical user interfaces, we identified key considerations for developing converged medical devices. Based on an analysis of domestic and international usability engineering activities and policies, we proposed strategies for the efficient development of converged medical devices.

2. MATERIALS AND METHODS

2.1 Converged Neonatal Incubator Design Process

Among the converged medical devices proposed in this study, the design process of a converged neonatal incubator was selected to apply the converged medical device design process. Among various converged medical devices, the focus was placed on the development of an incubator for the neonatal intensive care unit(NICU), which enables efficient utilization of medical devices in emergency situations.

The NICU environment uniquely combines the characteristics of an intensive care unit, catering to critically ill patients, and a surgical environment, where urgent procedures may be required. In this context, the converged neonatal incubator being developed in this study is not a stand-alone incubator; instead, it integrates a patient monitoring system, a warmer, and phototherapy that are essential medical devices needed in the NICU environment.

To develop such a device, the design process was approached from both systems and software perspectives. Specifically, the user interface was evaluated, refined, and designed according to the methodology outlined in Figure 15, ensuring seamless integration of the various functionalities. The system aspect refers to the external components of the device, such as the incubator or infant warming device, while the software aspect pertains to the display interface. To determine whether the converged device offers enhanced usability compared to existing devices, iterative usability evaluations are essential. The usability of each system and software component is assessed individually, along with the usability of the combined system-software interface, to ensure that the device provides cohesive and efficient user experience.

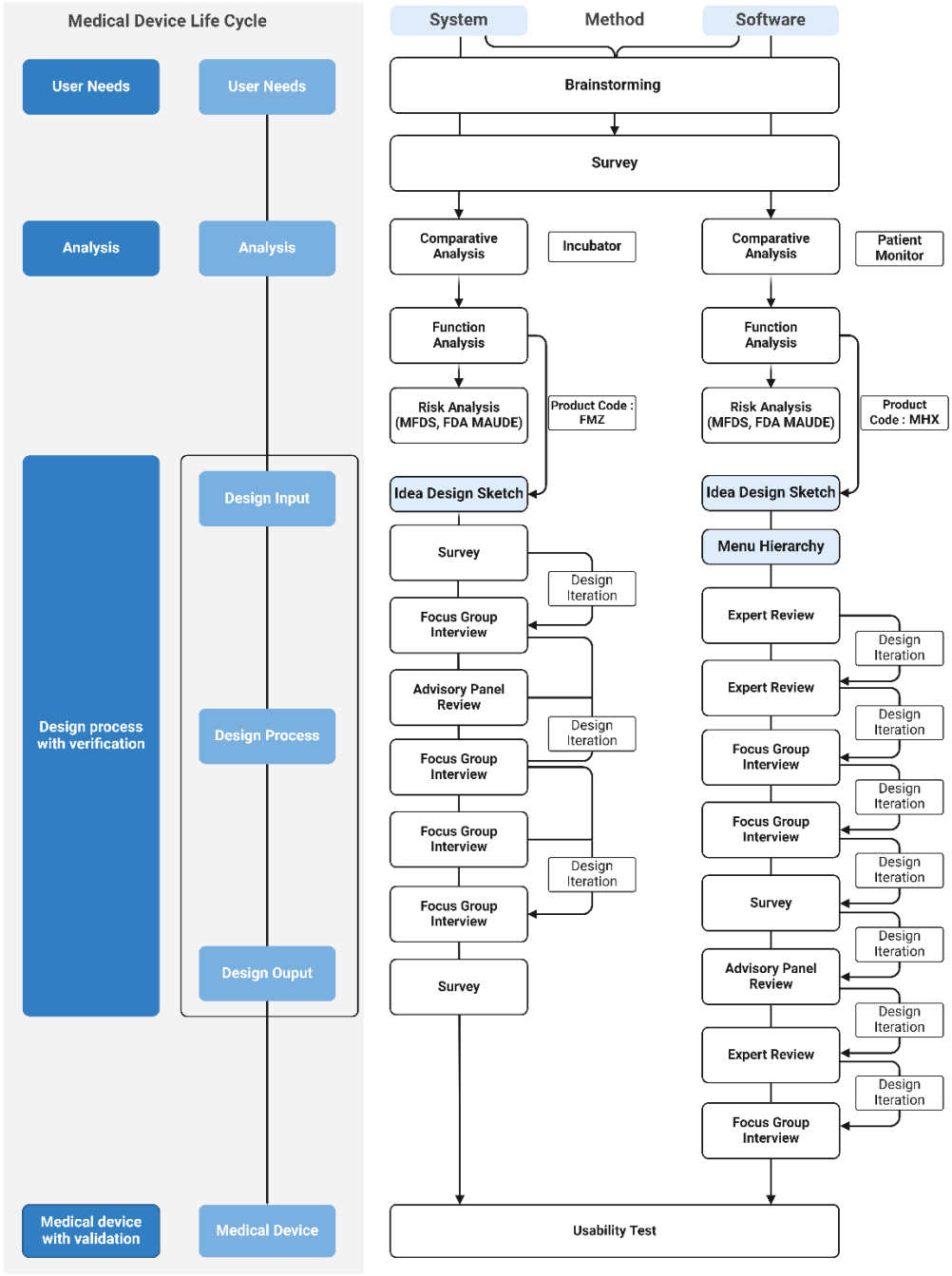


Figure 15. Life Cycle Process of Converged Neonatal Incubator

2.3.1 User Needs

1) Use Specification

When developing a medical device, it is essential to clearly identify the intended users and the environment in which the device will be used. For the incubator being developed, the intended users are NICU medical staff, including pediatricians and nurses, and the environment of use is the NICU. NICUs are designed to care for premature, ill, or high-risk newborns, playing a critical role in the treatment of these infants. In neonatal intensive care units, the temperature should be maintained between 22℃ and 26℃, with humidity levels between 30% and 60%[12]. Additionally, according to KSA 3011, the standard for illuminance in NICUs is 10-600 lx, and noise levels should be kept at 40 dB [12, 33, 34].

2) User Requirements

After identifying the intended users and use environment of the device, user requirements were gathered from the prospective users of the device under development. Clinical requirements were collected using a brainstorming method involving six pediatricians and two nurses. The collected requirements were then categorized by importance and frequency of use. Importance was assessed based on the necessity and value of introducing each feature into clinical settings. Frequency of use was an indicator reflecting how often similar functions are used or related actions are performed in clinical environments. Following the survey, the average and standard deviation for each item were calculated. Requirements were specified by taking into account the manufacturer's technical capabilities and the patents of existing third-party products. Ultimately, requirements that could be feasibly integrated into the final design were identified.

2.3.2 Analysis

After analyzing user requirements, comparative analysis, function analysis, and risk analysis were conducted, divided into system and software aspects according to the characteristics of the converged medical device being developed. As shown in Figure 16, we categorized the devices into incubators and patient monitoring systems, examining the product name, manufacturer, item classification, user interface, graphical user interface, and other relevant details for each similar device. Subsequently, information on side effects for the investigated products was reviewed, and hazards were analyzed.

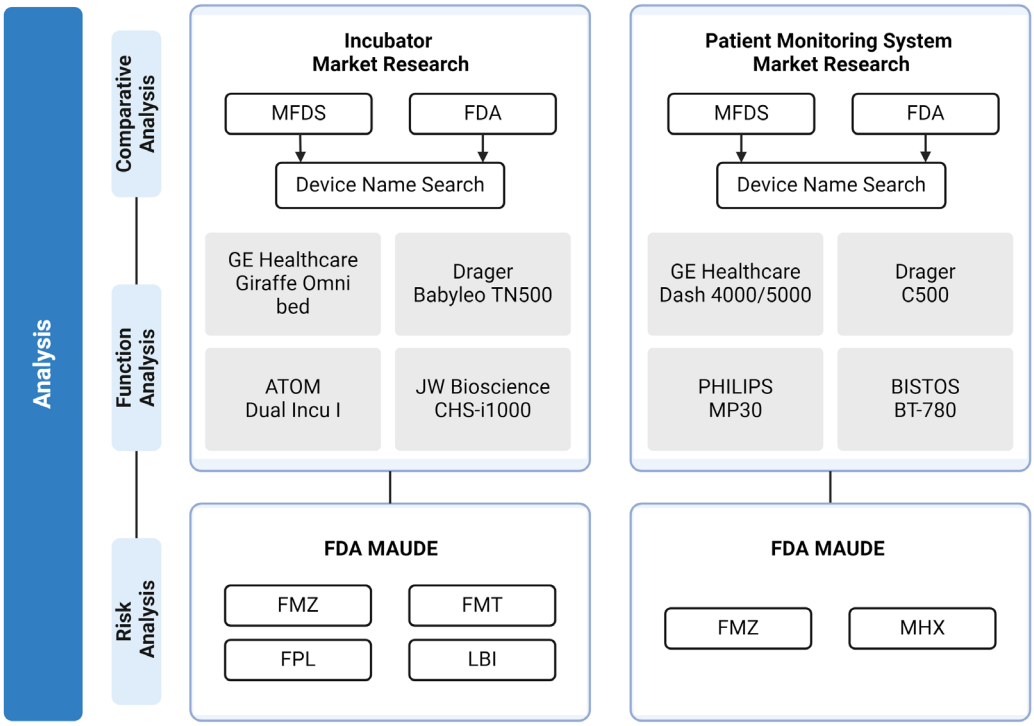


Figure 16. Analysis Process of Converged Neonatal Incubator

1) Comparative Analysis

A survey to list similar devices of the converged medical device being developed was done in two aspects: system and software. In order to observe the real clinical setting and find comparable devices currently in use, we also went to the NICU at Severance Hospital. The Ministry of Food and Drug Safety website was used to find comparable devices for domestic items, and then user manuals from each manufacturer were examined. Similar items were found for foreign medical devices using the FDA's Product Classification, and the devices were analyzed using the user manuals found on each company's website, much like for domestic products.

- System

A survey was conducted on similar domestic and international incubators and warming devices. For incubators and warming devices, the workflows of GE Healthcare's Giraffe OmniBed, Drager's Babyleo TN500, ATOM's Dual IncuI, and JW Bioscience's CHS-i1000 were examined. Additionally, for phototherapy devices, OHMEDA Medical's BiliBlanket Plus and GE Healthcare's BiliSoft 2.0 were investigated.

- Software

For the software aspect, we examined the display software of incubators and a patient monitoring device that tracks vital signs. Similar devices were studied to integrate the graphical user interface of the patient monitoring device and the incubator into a single screen. However, no converged devices were found during the investigation. For patient monitoring system, we analyzed the graphical user interfaces of BISTOS' BT-780, GE Healthcare's Dash 4000/5000, Philips' MP30, and Dräger's C500. For incubators, the investigation was conducted from a system perspective, focusing on GE Healthcare's Giraffe OmniBed and Dräger's Babyleo TN500.

2) Function Analysis

Based on clinical requirements, a functional analysis of similar devices was conducted. Function analysis is a testing method that examines the functionality of a medical device, helping to understand the respective roles of the user and the device in its overall use. The devices to be developed incorporate standards from IEC 60601-2-19 (Infant Incubators), IEC 60601-2-20 (Infant Transport Incubators), IEC 60601-2-21 (Infant Radiant Warmers), and IEC 60601-2-50 (Infant Phototherapy Equipment, for treating neonatal jaundice), which include requirements for devices that integrate multiple functions. These standards are applied accordingly to meet the necessary specifications.

- System

We determined the specifications for the device under development by inspecting the heating technique, weight and size, cable configuration, weight measurement method, mattress form and mechanism, and incubator and warming device capabilities.

- Software

Each device's operations were analyzed in order to design a graphical user interface. The bio signals were examined in terms of basic waveforms, parameter types, display size, data storage, alarms, and alarm prioritization.

3) Risk Analysis

The medical device usability standard IEC 62366 and the medical device risk management standard ISO 14971:2019 both need risk analysis as a crucial element. The methodical identification and mitigation of any risks related to the use of medical equipment is the goal of this process. The U.S. FDA emphasizes the importance of risk analysis in its latest guidance, "Content of Human Factors Information in Medical Device Marketing Submissions," which underscores the need to identify critical task during risk analysis. The guidance additionally points out the need to look into documented safety problems for similar devices by doing hazard analyses using the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.

To incorporate relevant information into this study, we conducted a hazard analysis by reviewing FDA MAUDE data, recall records, and adverse events and safety information from the Korean Ministry of Food and Drug Safety. The item codes used during the search are listed in Table 6.

Table 6. FDA Product Code for Converged Neonatal Incubator

Device	Product code	Device class
Incubator, neonatal	FMZ	II
Incubator, neonatal transport	FPL	II
warmer, infant radiant	FMT	II
unit, neonatal phototherapy	LBI	II
monitor, physiological, patient (with arrhythmia detection or alarms)	MHX	II

Based on FDA MAUDE data, we analyzed use errors reported in similar devices and identified hazards that could impact the safety and efficiency of the device under development. These identified factors were incorporated into the device design, which was subsequently improved to proactively prevent similar hazardous situations. Once design improvements were completed, a use scenario was developed, and a summative evaluation was conducted based on the identified hazards. Conducting an evaluation that addresses these hazards helps to ensure user safety and minimize potential risks.

2.3.3 Design Process with Verification

In the “Design Process with Verification” stage, a user interface was developed based on the data obtained from the Analysis stage, divided into system and software components. As shown in Figure 17, a total of seven formative evaluations were conducted for the system, while the software interface was designed using Adobe XD and underwent iterative refinement. The design was improved multiple times, with a total of 15 formative evaluations performed.

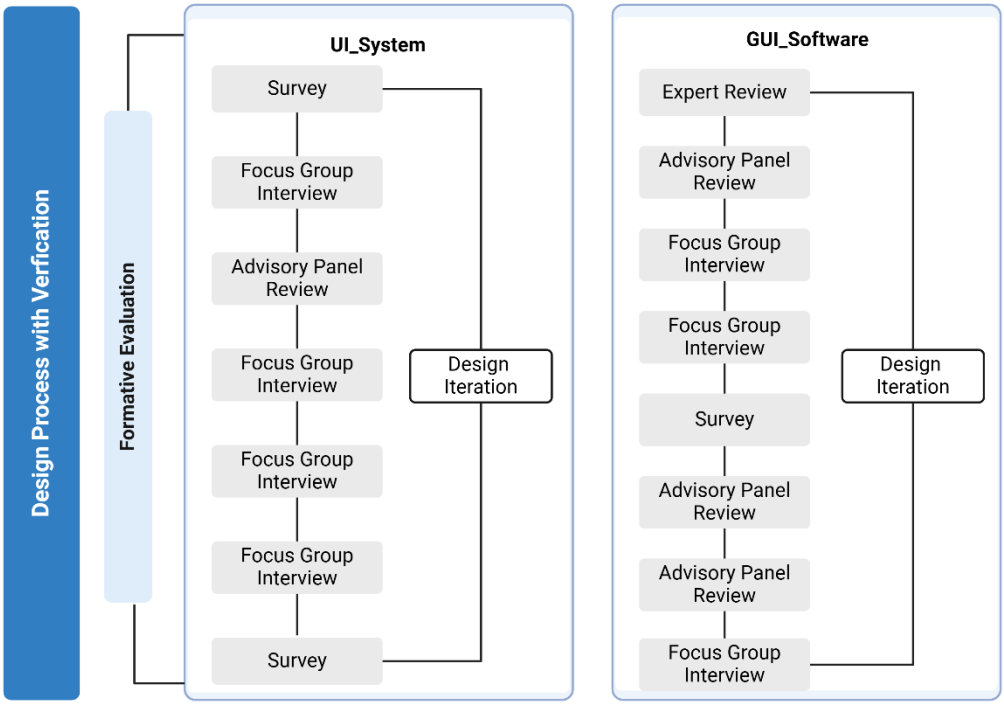


Figure 17. Design Process with Verification of Converged Neonatal Incubator

1) System

Seven formative evaluations were conducted by NICU medical staff and usability experts, the actual users of the device under development to develop and enhance the design of an incubator that integrates system-related patient monitoring, heater, and phototherapy. Usability evaluations were performed on 12 drafts, each designed to incorporate research on similar devices and clinical requirements, ultimately leading to the final draft.

- Survey

The survey method has the benefit of being a quick testing strategy since it uses structured survey questions to collect crucial data from medical device users. Two survey methodologies were used in this study: the first one concentrated on the incubator's initial look and user interface. A survey about the exterior buttons on the LCD display was sent to the NICU medical staff as part of the seventh formative evaluation of the system.

- Focus Group Interview

Focus Group Interview is a method where groups of participants, such as doctors, nurses, and ergonomists, come together to discuss and respond to topics provided by a facilitator[35]. In this study, actual users of the device, including intended users, NICU medical staff, and usability experts, gathered to refine the design by providing feedback on the device’s appearance and user interface through four focus group interviews. User interface improvements were identified through this method during the 2nd, 4th, 5th, and 6th formative evaluations.

- Advisory Panel Review

Advisory Panel Review is a testing method where an advisory group, consisting of representative medical device users, discusses the user, environment, design elements, and potential risks of the medical device[35]. The advisory group must include actual users to accurately capture user characteristics and needs. This method can be applied at any stage of medical device development, from the initial design concept to a fully developed product. In this study, we finalized the design proposal during the third formative evaluation through an advisory panel review with NICU medical staff.

2) Software

The graphical user interface (GUI) of the device under development was created through comparative and functional analysis of GUIs from similar patient monitoring devices and incubators. As shown in Figure 18, the screen was designed using Adobe XD, a prototyping tool for GUI development. Interactive prototypes with defined screen paths were created to simulate and test the designed interface, enhancing the overall UI/UX. To simulate the design, a shareable link was provided to users, allowing them to interact with the interface by pressing buttons, and the usability of the screen was reviewed based on their feedback. In the case of Adobe XD tools, rather than just looking at a screen, the auto-enimate feature allows you to switch between screens to give a realistic feel and is useful for developing early prototypes and performing usability evaluation.

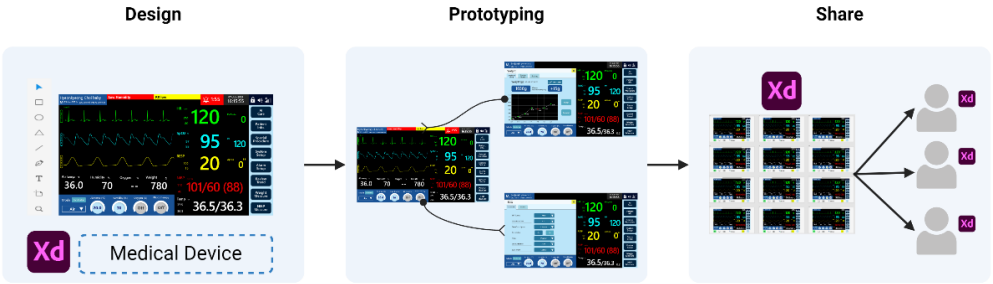


Figure 18. UI/UX Design Flow with Adobe XD

Usability was enhanced through eight formal evaluations with NICU medical staff and usability experts. The graphical user interface, color, size, and placement were designed in accordance with ANSI/AAMI HE 75:2009 (R2018) standards. The usability evaluation method used to improve the software's graphical user interface is as follows.

- Expert Review

Expert Review is a testing method that involves consulting usability experts to assess the usability of medical devices[35]. Conducting an expert review allows for the identification of the device's strengths and weaknesses, as well as potential use errors, based on expert feedback. This method was utilized during the 1st, 2nd, and 7th formative evaluations. Through expert input, the graphical user interface was refined from four initial drafts designed in Adobe XD down to a single draft, enhancing usability based on expert recommendations.

- Focus Group Interview

Formative evaluation was conducted through three focus group interviews, during which NICU medical staff and usability experts gathered in the 3rd, 4th, and 8th formative evaluations to provide feedback on improving the graphical user interface.

- Survey

Formative evaluation was conducted using the survey method, with an online survey targeting NICU medical staff during the 5th formative evaluation. The online survey included a 5-point Likert scale satisfaction survey and a SUS (System Usability Scale) survey. The SUS survey consists of 10 questions and assesses the overall usability of the system[26, 36, 37].

- Advisory Panel Review

A formative evaluation was conducted using the advisory panel review method. During the 6th formative evaluation, NICU medical staff were consulted on the canopy system method, the external temperature/humidity display of the incubator, and the naming of incubator modes.

2.3.4 Medical Device with Validation

The final design was developed through the stages of User Needs, Analysis, and Design Process with Verification, and this stage is focused on validating that it meets the user's requirements. The user interface and graphical user interface were developed through multiple design processes. A summative evaluation is carried out on the developed converged neonatal incubator, as shown in Figure 19.

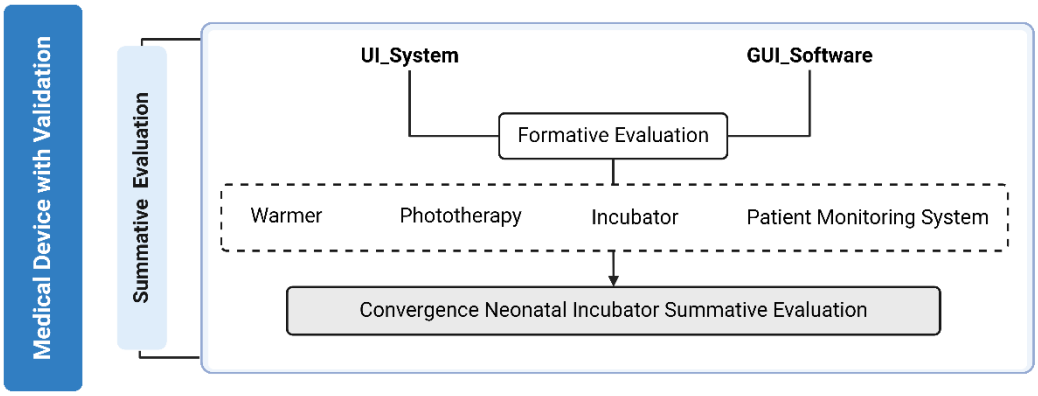


Figure 19. Design Process with Verification of Converged Neonatal Incubator

- Usability Test

Usability test involves observing and testing the use process based on scenarios developed through task analysis by the intended users of the device in a simulated environment [35]. This method is the most commonly used evaluation approach in summative evaluation, and according to IEC 62366 standards, it must be conducted with a minimum of 15 participants. In this study, a simulated NICU environment was created for 15 NICU medical staff to evaluate the device's usability.

3. RESULT

3.1 Converged Neonatal Incubator Design and Development

3.1.1 Elicitation Needs of Intended Users

As shown in Figure 20, the intended user and patient group were identified for the development of the convergence incubator. The intended patient population for the incubator, infant heater, and phototherapy is neonates and premature infants, while the patient monitoring target includes both adults and neonates. The representative patient population for all four devices is premature and low birth weight infants, with the intended users being NICU staff.

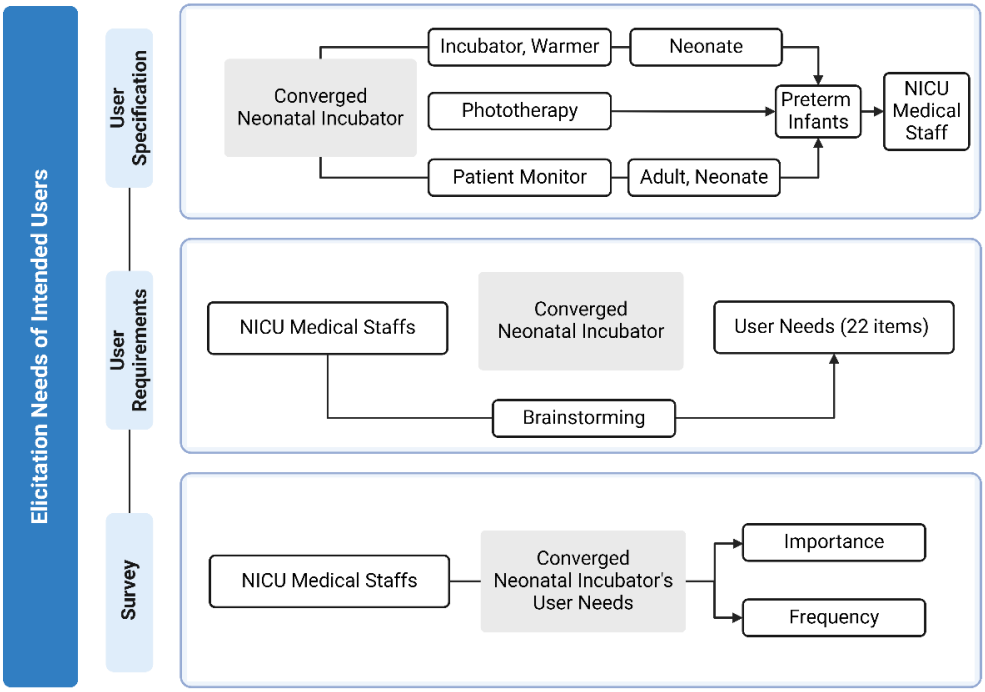


Figure 20. Intended User Requirements Elicitation Process

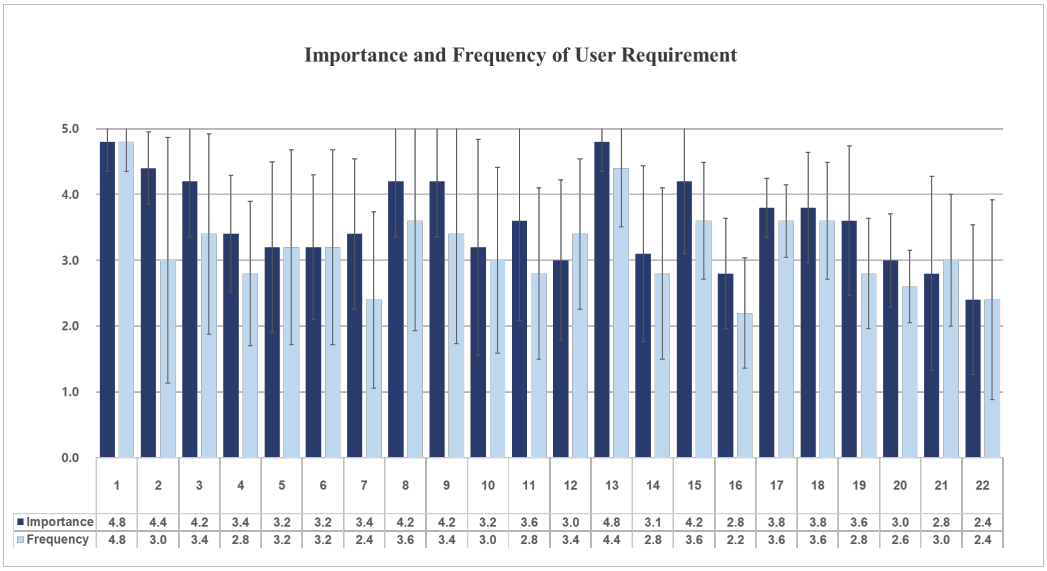
In this study, following the “User Requirements” stage in Figure 20, the incubator, infant heater, phototherapy, and patient monitoring systems were integrated through brainstorming sessions with eight pediatricians and nurses from the Severance Hospital NICU medical staff. User requirements for the medical devices were derived, as shown in Table 7.

Table 7. User Requirements for Convergence-Based Incubator

No	User Needs	Definition
1	Apnea Intervention Alarm	• In the event of a bradycardia or apnea, an alarm alerts the user as to whether intervention or stimulation is necessary
2	Auto Stimulation	• When apnea requires stimulation occurs, the stimulator built into the incubator provides appropriate stimulation
3	Built-in Stimulator	• A built-in stimulator (e.g., tactile stimulator, vibrator) is included in the incubator
4	Flipping , Sliding View for Vital Signs	• Patient monitoring parameters, such as HR, Saturation, RR, and BP, are displayed on the incubator screen. If all parameters cannot fit on one screen, the screen can be configured to switch between them
5	Weight Record Review	• The weight measured in the incubator can be directly viewed on the incubator monitor
6	Non-contact Body Temperature Measurement	• Peripheral body temperature is measured with a non-contact sensor, such as an infrared camera
7	Earplug for Noise Prevention & Temp Measurement	• Body temperature is measured and noise is minimized simultaneously by attaching a body temperature sensor to noise-canceling earplugs
8	Weight Calibration without Lifting Baby	• Weight can be measured without lifting the patient for calibration, eliminating the need to reposition the patient on the mattress after measurement. Movement of the mattress or other equipment does not require lifting the patient each time weight is measured

No	User Needs	Definition
9	Auto Measurement of Diaper	• Diaper weight is automatically subtracted, displaying only the patient's weight without the need to remove the diaper
10	Mattress Tilting (Left & Right)	• The entire mattress tilts left and right in addition to the traditional up-and-down tilting of the head section
11	Height Compatibility with Transportable Incubator	• The patient can be transferred from the transport incubator by sliding from the side without lifting
12	Cabinet Location at Hand Level	• Storage compartments are positioned at a convenient hand height
13	Drawer of X-ray Detector under Incubator	• The drawer for the x-ray plate is located separately on the bottom of the incubator, rather than under the mattress, to avoid having to open the incubator to access the x-ray plate
14	Holding Bag Type Humidity Bottle	• Humidity Bottle is designed to be hung like a fluid bag, similar to a ventilator
15	Self-Oxygen Control	• Oxygen control function is integrated directly into the incubator.
16	Built-in Wrapping Material	• Built-in wrap system for temperature and humidity control of the newborn inside the incubator
17	Rotatable Mattress	• 360-degree rotatable mattress
18	Door Alarm	• Alarm sounds if the door is left open for an extended period or if the IV line becomes pinched in the door
19	Separated Heating Area in Mattress	• The mattress includes zoned heating elements, allowing for temperature control by specific zones, similar to Dräger's incubator
20	Availability with Biliblanket	• Blanket designed to be thin enough for use within the incubator
21	Negative Pressure with Gomco Suction	• Built-in suction feature capable of applying negative pressure.
22	Hypothermia	• Temperature-lowering function is designed to provide gradual cooling.

Based on user requirements, a survey was conducted with five neonatal intensive care unit medical staff to assess the importance and frequency of use of various functions. Figure 21 presents the mean and standard deviation for the importance and frequency of use across 22 user requirements. While the average score for frequency of use was 3.2, the overall average score for importance was 3.6. With an important score of 4.80 (0.45), the Apnea Intervention Alarm and the Drawer for X-ray Detector under the Incubator were the two items with the highest ratings among the user needs. These items had corresponding frequency of use values of 4.80 (0.45) and 4.40 (0.89).



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Importance	4.8	4.4	4.2	3.4	3.2	3.2	3.4	4.2	4.2	3.2	3.6	3.0	4.8	3.1	4.2	2.8	3.8	3.8	3.6	3.0	2.8	2.4
Frequency	4.8	3.0	3.4	2.8	3.2	3.2	2.4	3.6	3.4	3.0	2.8	3.4	4.4	2.8	3.6	2.2	3.6	3.6	2.8	2.6	3.0	2.4

Figure 21. Importance and Frequency of User Requirement

Among the requirements with an overall average score of 3.6 or higher for the importance of the 22 items, there are three items that are challenging to incorporate into the actual design. For item 11, the converged incubator being developed is a mobile incubator, so this function is already included and does not require separate integration. Since GE's 360-degree rotation technology for item 17,

the Rotatable Mattress, is patent protected, it cannot be utilized in other domestic or international devices. Additionally, item 19, which calls for a mattress that generates heat, could not be included in the design.

Although item 12, the requirement for a drawer positioned at hand height, scored lower than 3.6 in importance, it is planned to be incorporated into the external design by using a shelf instead of an additional drawer, as there is already a drawer at the bottom of the incubator.

In medical device development, it is crucial to derive requirements from actual users, such as medical staff, and evaluate whether these functions align with the patent limitations. Through this approach, importance and frequency of use were comprehensively assessed to determine the feasibility of each requirement, guiding the incorporation of applicable functions into the design of the converged medical device.

3.1.2 Comparative Analysis of Similar Medical Devices

1) User Interface Design Analysis

As shown in Table 8, the functions and features of incubators, warming devices, and phototherapy devices were analyzed. Due to the characteristics of the incubator, measurements could be taken for air temperature, skin temperature, humidity, oxygen levels, and weight. For GE Healthcare's Giraffe OmniBed, the mattress inside the incubator could rotate 360°, whereas other similar devices did not have this rotation capability[38].

Table 8. Comparison of Features and Specifications of Similar Incubator Devices

	Giraffe Omni bed	**Babyleo TN500**	**Dual Incu I**	**CHS-i1000**
Manufacturer	GE Healthcare	Drager	ATOM	JWBioscience
Device size (Width*Depth)	1140*660	1154*690	1190*680	1016*642
Device size (Height)	1520 to 1780	1850 to 2250	1380*2260	1520*1798
Device Weight	149kg	<140kg	132kg	130kg
Display size	264mm	264mm	216mm	264mm
Mattress Rotation Angle	360°	0°	0°	0°
Inclination of the Mattress Tray(Tilting)	12°	13°	13°	12°
Function	• Air/Skin Temperature Regulation • Humidity /Oxygen Regulation • Weight			

2) Graphical User Interface Design Analysis

The graphical user interface of the patient monitoring systems was examined to develop a software design tailored to the characteristics of converged medical devices. Upon analyzing products from four companies, it was observed that the waveform and numeric display areas were separated. However, differences were found in the display operation methods, alarm message locations, and alarm indicator colors. The details are listed in Table 9.

Table 9. Comparison of Features and Specifications of Similar Patient Monitoring Systems

Device Name	**Dash 4000/5000**	**MP30**	**C500**	**BT-780**
Manufacturer	GE Healthcare	Philips	Drager	Bistos
Function	• ECG, RR, SpO2, NIBP, Temp • Alerts (messages, indicator lights, audible signals), trend reviews			
Display size	12.1 inch	10.4 inch	17 inch	15.6 inch
Display Features	Knob	Touchscreen, Knob		
Maximum Waveform Capacity	6	8	16	7
Alarm pause time	3 min	2 min	2 min	2 min
Alarm Message Display Location	Bottom	Top	Top	Top
Alarm Indicator Light Color	Red	Red, yellow, cyan		Red, yellow

In the comparative analysis stage, similar equipment such as incubators and patient monitoring devices were investigated and analyzed, followed by a function analysis. For the graphical user interface, screen elements must include items related to both the incubator/infant heater device and the patient monitoring system. Each function of the incubator and patient monitoring system was analyzed in detail, including the sub-menus within each menu. Methods for accessing each menu

were also identified to support actual development.

Table 10 provides a functional analysis to identify requirements within neonatal incubators and patient monitoring devices. Both neonatal incubators and patient monitoring system feature patient management and alarm functions. Since the patient monitoring device primarily tracks vital signs, the main parameters focused on were centered on vital signs. For neonatal incubators, parameters such as humidity, temperature, oxygen, and body weight were emphasized. Additionally, the incubator included a mode-switching function to manage body temperature through both incubator and warmer modes, consistent with its primary role of temperature maintenance.

Table 10. Comparative Functional Analysis of Neonatal Incubators and Patient Monitoring Devices

Neonatal Incubator/Warmer		**Patient Monitoring System**	
Patient Management	• New Patient • Current Patient	Patient Management	• New Patient Admit • Patient Discharge
Incubator Operation	• Settings • Operation Mode	Review Trend	• Graphic Trend • Tabular Trend • OXY-CRG • Alarm History • Drug Dosage Calculation
Radiant Operation	• Prew-warm Mode • Settings • Operation Mode	Display Setting	• Display Mode • Lock • Power On/Off
Kangaroo Mode	• Setting Skin Temp • Alarm Limit	General Setting	• Sound Setting • Language Setting • Network Setting • Unit Setting • System Setting
Skin Temp	• Setting Target Skin Temp • Alarm Setting	Maintenance Mode	• Demo Mode • Date and Time • Module

Neonatal Incubator/Warmer		Patient Monitoring System	
Air Temp	• Setting Target Air Temp • Alarm Setting	Parameter 1 (ECG)	• Waveform Setting • Arrhythmia Analysis Setting • ST Analysis Setting • Alarm Setting
Humidity	• Setting Target Humidity Level	Parameter 2 (SpO2)	• Waveform Setting • Alarm Setting
Oxygen	• Setting Target Oxygen Concentration • Alarm Setting	Parameter 3 (Resp)	• Waveform Setting • Alarm Setting
Scale	• Weighing • Adjusting the Measured Patient Weight	Parameter 4 (NIBP)	• Measurement Setting • Alarm Setting
Taking X-ray	-	Parameter 5 (Temp)	• Alarm Setting
Alarm	• Alarm Priorities and Alarm Signals • Alarm History	Alarm	• Parameter Alarm Setting (ECG, SpO2, RESP, NIBP, TEMP)

In Table 11, as well as in Table 10, to develop a graphical user interface for a converged incubator through functional analysis within the neonatal incubator and patient monitoring device, detailed functions within each item were analyzed, and a control method was determined.

The display parameters for the converged medical device under development were considered to be a 15.6-inch touch screen by comparing and evaluating the operations of similar devices. Usability evaluation was then used to decide where the parameters, waveform, numerical values, and alarm indication light should be placed.

Table 11. Functional Requirements Analysis for a Converged Neonatal Incubator (Part)

Function		Option	Action/Display
Patient	Admit	OK / Cancel	Alert Message
	Patient Information	Last name / First name / Patient ID / Patient Type / Gender / Birthdate / Age / Height / Weight	Keypads / Buttons in New window
	Discharge	-	Alert Message
Operation	Incubator	On / Off	Button
	Warmer	On / Off	Button
	Kangaroo	On / Off	Button
Review	Alarm History	Technical / Physiological / Priority Level / Date / Time	Table
	Graphic Review	HR / PVCs / SpO2 / PR / RESP / Temp(Skin-1, 2, Skin-D, Air) Humidity / Oxygen / Weight	List
	Tabular Review	HR / PVCs / SpO2 / PR / RESP / Temp(Skin-1, 2, Skin-D, Air) Humidity / Oxygen / Weight	List
	OXY-CRG	HR / SpO2 / RESP	Waveform
Alarm	Parameter	ECG / SpO2 / RESP / NIBP / TEMP	Tab
	Alarm On/Off	On / Off	Buttons in New window
	HR	Upper Limit / Lower Limit	Radio Button
	SpO2	Upper Limit / Lower Limit	Radio Button
	Resp	Upper Limit / Lower Limit	Radio Button
	NIBP	Upper Limit / Lower Limit	Radio Button
	ST	Upper Limit / Lower Limit	Radio Button
	Arrhythmia	Upper Limit / Lower Limit	Radio Button
	Skin Temp	Upper Limit / Lower Limit	Radio Button
	Air Temp	Upper Limit / Lower Limit	Radio Button
	Humidity	-	Radio Button
	Oxygen	-	Radio Button

3) Risk Analysis of Converged Medical Devices

Since this device is a converged medical device, hazards and risk situations for each medical component were investigated and analyzed through PMS (Post-Market Surveillance) data from the FDA MAUDE (Manufacturer and User Facility Device Experience) database. For incubators, data on hazards and risk situations from January 1, 2006, to December 31, 2022 were collected and analyzed. For warming devices and phototherapy equipment, data from the most recent three years were analyzed. In the case of patient monitoring devices, PMS data reported from January 1, 2021, to June 30, 2023, were examined, and 192 usability-related PMS cases were analyzed from a total of 4,325 PMS entries. Table 12 presents selected results from the research and analysis of PMS data.

The most common hazardous situation in incubators involved patients falling or suffering harm when the side door was opened. This often occurred due to improper installation or loosening of the locking mechanism. Additionally, in warming devices or phototherapy, incidents of patient injury due to overheating were reported. These risks could be mitigated by adjusting light intensity, including relevant information in the user manual, and implementing audio-visual alarm indicators. The most critical hazard was errors within the alarm system. Delays in identifying alarms during emergencies, such as when the alarm message was only visually shown without an audio sound, or vice versa, were the cause of numerous use problems that were recorded.

To develop a converged medical device, the hazards of similar devices for each component must be analyzed and incorporated into the design. The most frequently occurring issues should be addressed in design improvements and usability evaluations to enhance overall usability.

Table 12. Adverse Event Investigation in Converged Medical Devices

Product code	Hazard	Hazardous Situation	Improvement
FMZ	Side door	• The side door of the incubator was opened, causing the patient to fall and sustain a head injury	• A lock and alarm message are displayed when the side door of the incubator is opened
	Humidity	• Burns caused by the humidity bin	• A caution symbol is placed next to the humidity container
	Canopy	• The canopy locked, trapping the patient for 20 minutes	• Hazardous situations can be addressed in two ways: using physical buttons and the touch screen
FMT	Over heating	• The temperature of the warming device was high, but the alarm did not sound	• In case of overheating, a visual/audible alarm displays the patient's temperature
LBI	Over heating	• Overheating can cause burns or skin inflammation in the patient	• Include an indicator for intensity control • Overheating precautions are listed in the user manual
MHX	Alarm	• When an SpO_2 alarm occurs, pressing the alarm pause button clears the alarm, leading to patient injury	• Since the patient's alarm review record is important, alarm review is enabled, and the pause and delete buttons are designed to be distinct
	Device Falling	• The device falls on the patient's head	• When designing the incubator monitor, prevent the risk of falling by securing the monitor arm

3.1.3 Design Iteration with Verification

1) User Interface Design Iteration

The incubator design was developed based on research and analysis of similar products and was refined through a total of seven formative evaluations, as shown in Figure 22. During this process, the design underwent significant improvements, resulting in enhancements to the design elements of each component, including the incubator's appearance. In the initial formative evaluation, preferences for various designs were surveyed among NICU medical staff, which ultimately led to the development of the final user interface.

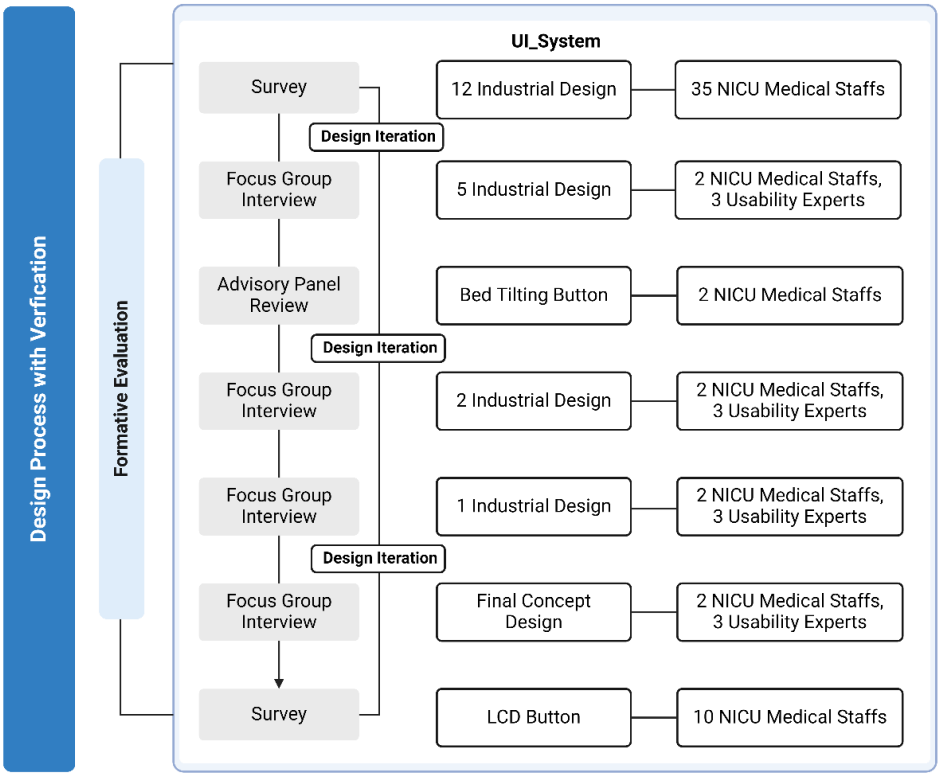


Figure 22. User Interface Design Iteration

A user interface was designed based on user feedback on the design approach for each component of the product, followed by a usability evaluation. Using 12 industrial design (ID) drafts created by a design company, a survey was conducted with 35 NICU medical staff (10 doctors, 15 nurses), the intended users, to gather feedback on the drafts and product components. When developing an incubator, the priorities in terms of design were ranked as follows: functionality, usability, space efficiency, and aesthetics.

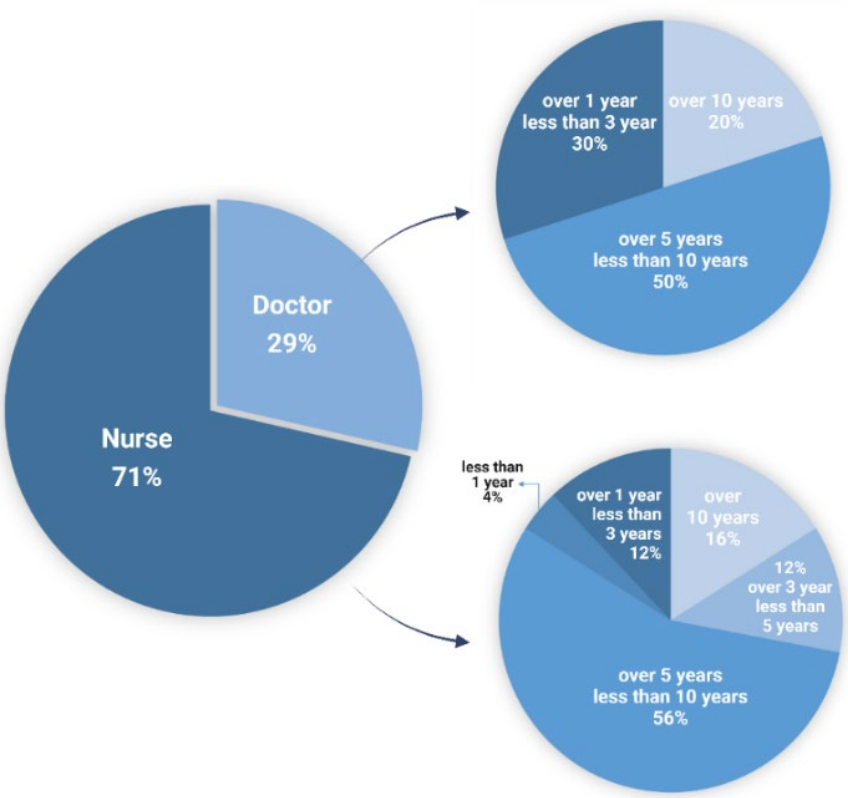


Figure 23. Participant Information for 1st Formative Evaluation

A preference survey was conducted based on 12 drafts divided into 3 groups, with 42.4%, 36.4%, and 61.6% of participants selecting one draft from each group, as shown in Table 13.

Table 13. Preference Results for Each Incubator Industrial Design

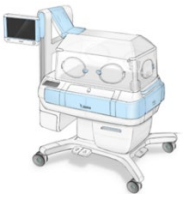
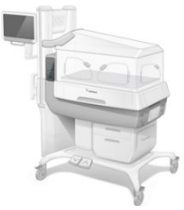
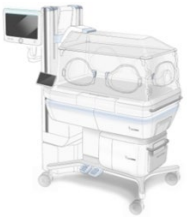
Category	Response Rate	Feedback	Image
Design Group 1	42.4%	• Overall balance with excellent functionality and aesthetics • The monitor alarm indicator light is appropriately positioned, and storage space is sufficient	
Design Group 2	36.4%	• Storage is convenient with two-tiered storage, though the size of the hand port needs improvement	
Design Group 3	61.6%	• Monitor alarms and other features are well-positioned with good visibility • Footswitch and handle are adequate	

Table 14 presents the results of preferences for each component of the incubator. Due to the nature of the NICU, it is a complex environment with various medical devices, making intuitiveness and visibility of devices highly important. Recognizing alarms for patient incidents is essential for timely intervention and treatment, so it is crucial to position the alarm indicator light at the top to avoid obstruction by other medical devices. We plan to research and analyze preferences for each incubator component from a usability perspective and incorporate these findings into the user interface.

Table 14. Results of Design Preference for Each Incubator Component

Category	Preference	Response Rate	Feedback
Canopy, Warmer operation	Canopy (rail) Heating (single hinge)	70.6%	• Easy to open and close, with adjustable height for optimal space utilization
Warmer module	Positioned around the patient, adjustable positioning.	51.6%	• Preferably, the heating lights should be either dual or adjustable, allowing positioning around the patient rather than directly above
Canopy shape	Flat, wide shape	45.2%	• Allows easy observation
Monitoring indicator location	Top	82.4%	• With a lot of equipment in the NICU, it is likely to be more visible if positioned at the top
Hand port shape	Small	48.5%	• The door should not be too large, as opening it may cause temperature/ humidity to drop
Side door	straight 180-degree opening shape	35.5%	• The door design allows unrestricted access for medical staff to provide treatment, and an x-ray insertion port has been developed, making it convenient for imaging
Humidity	Front (middle)	60.6%	• Placing the water reservoir at a mid-level makes it easier to check and replace, as opposed to a lower position.
Bed tilting button	Physical button	85.7%	• Touch screens are prone to misoperation; therefore, buttons are preferred
Handel location	Top of the front	45.5%	• Prefer a location that is easy to grasp for movement
Handel shape	Single protruding type	67.4%	• Excellent grip and usability
Caster brake	Lock present on each wheel	40.0%	• Each wheel should be lockable to allow for easy movement and stability

Category	Preference	Response Rate	Feedback
Foot switch	Square shape with no protrusions.	42.4%	• There are no grooves, which appears to reduce risk
X-ray door	Separate door	37.5%	• Preferred because the x-ray plate is separate
Drawer	Two-tiered	54.5%	• Preferably as large as possible and divided into two tiers
Base & Leg	Plain form	53.1%	• Prefer materials that do not easily attract hair

As a result of a survey conducted with 35 NICU medical staff, 82.4% of respondents preferred the alarm indicator light to be located at the top, and 85.7% preferred a physical button rather than a touch screen for the mattress tilt adjustment button.

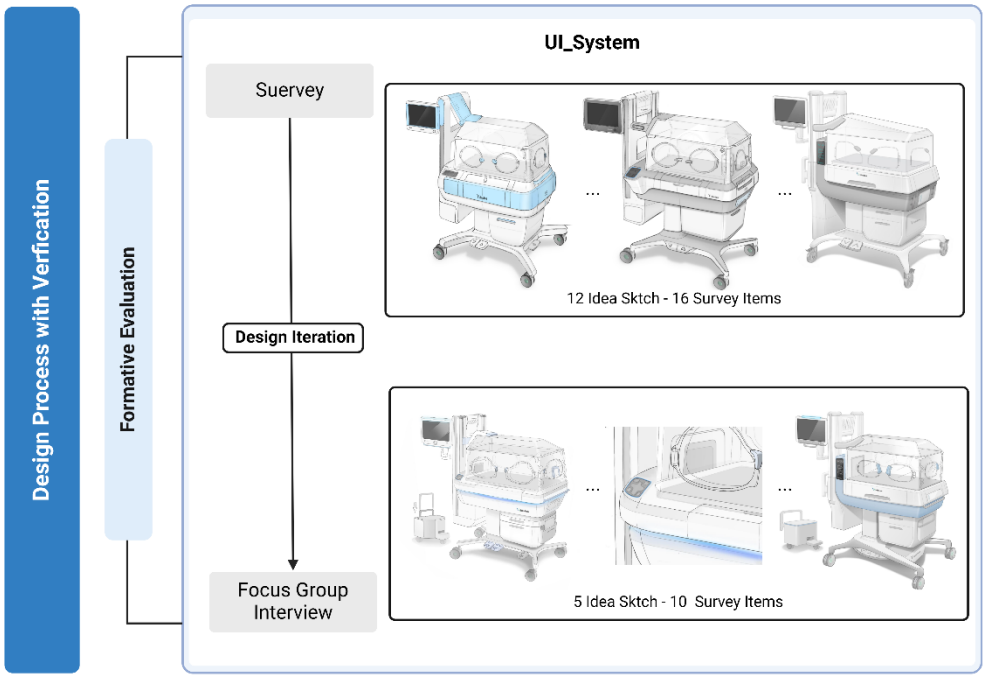


Figure 24. Formative Evaluation Process for Primary UI Design Improvement

Two NICU medical staff and three usability experts conducted a focus group interview, which was the second formative evaluation. Five drafts that incorporated feedback from the first formative evaluation was used during the focus group interview. Ten items were discussed, and detailed information is provided in Table 15.

Table 15. Preference Results for the Second Industrial Design

Category	Feedback
Shell	• The flattest shape is preferred to allow medical staff full access to the incubator when treating patients
Canopy	• The top of the canopy should be flat, with a wide base
Control panel handle	• It would be ideal if the monitor handle were not too long or thick and did not stand out in shape or color
Hand port	• An oval shape is preferred for ease of operation, allowing it to be opened and closed with the elbow • The hand port should remain open to prevent humidity from escaping, and a small porthole is preferred
Bed tilting	• Only up, down, left, and right buttons are needed, so a compact button design is sufficient • Buttons for adjusting the mattress up, down, left, and right, as well as a button to move the entire mattress, are considered necessary
Handle	• A preference for embossed handle shapes
Humidity	• Water storage capacity and internal design are more important than external appearance • It should have a capacity of 1L, and the lid should fully open and close
Drawer	• Satisfied with the size and shape of the two-tier drawer and the design with side pockets
Footswitch , caster break	• It is confusing if the footswitch and caster brake are aligned in the same direction, so different orientations are preferred
Base & Leg	• As there are newborns and various equipment, the device itself must be sturdy, and this design is preferred as it appears the most robust

The third formative evaluation used an advisory panel review method, with a usability evaluation conducted on the incubator's mattress movement button by two NICU medical staff. In the first and second formative evaluations, the focus was on the contact method of the bed tilting button; however, in the third formative evaluation, the usability evaluation focused on the scenario when the button is pressed and the button's placement.

This button was evaluated because newborns can also develop bedsores if they remain in the same position for extended periods, necessitating regular changes in the patient's position. The design of the mattress shape adjustment and bed tilting button for repositioning is shown in Figure 25. The tilting angle of the mattress can be adjusted up to 12°. Table 16 presents button use scenarios based on the mattress's inclination.

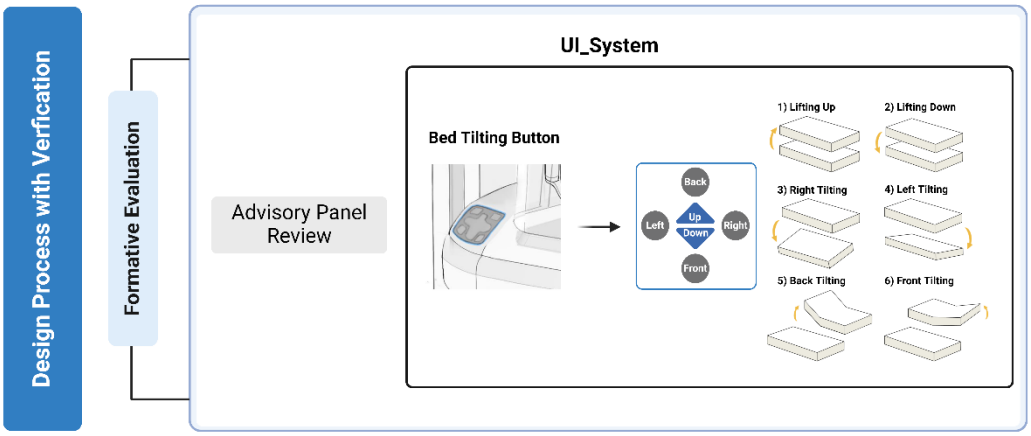


Figure 25. Method for Bed Tilting Button Operation

Table 16. Scenario for the Bed Tilting Button

No	Bed full up and down movement	Tilting in each direction
1	• Up/down key	• To raise, press the buttons in each direction individually; to lower, press the buttons simultaneously (e.g., press right to raise the right side, right + down to lower the right side)
2	• Up/down key	• Press sequentially (e.g., right to raise the right side → left to lower the right side)
3	• Up/down key	• Press the directional buttons to raise, and press the down button to lower (e.g., right to raise the right side → down to lower the right side)

Among the three scenarios, NICU medical staff preferred scenario number 3 the most, and it was suggested that a tilt release button and a button to return to the original position would enhance ease of use. Additionally, there was discussion about whether pressing the "Down" button should lower the mattress to a specific desired level or fully reset it to the default position. Similar devices typically have a button to return to the original position, so it was recommended to include this feature to increase familiarity and usability in the clinical environment. The user interface was improved based on feedback from the second and third formative evaluations.

Two NICU medical staff and three usability experts conducted two focus group interviews based on the third draft of two industrial design (ID) concepts created by a design company. In the fourth formative evaluation, an assessment was conducted on the overall appearance, hand port shape, drawer, and mattress rotation. In the fifth formative evaluation, an additional usability evaluation was performed, focusing on the back of the column, monitor, sensor cable, and caster lock.

The items and drafts evaluated in the fourth and fifth formative evaluations for the two drafts, which were improved based on the results of the third formative evaluation, are shown in Figure 26.

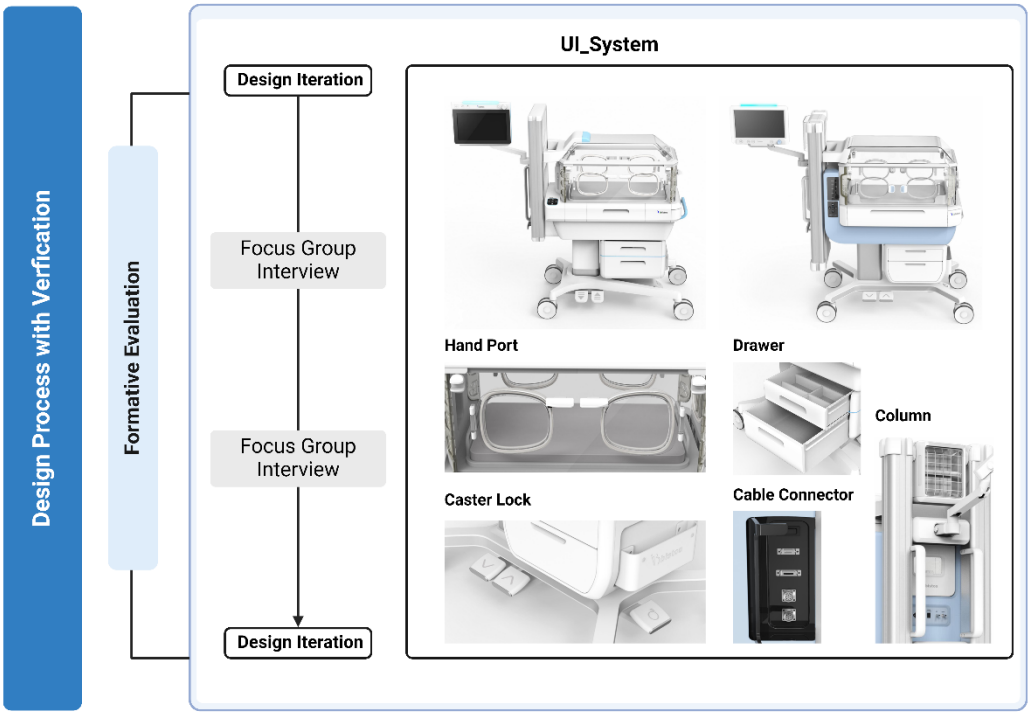


Figure 26. User Interface Iteration for the 4th and 5th Formative Evaluations

The shape of the control shell, the bed tilting button, and the display are where the two designs differ the most. The physical buttons and knobs are positioned differently, with some at the top and others at the bottom, even though the alarm indicator light at the top of the display is the same in both versions. Additionally, the location of the bed tilting button varies, and there is a distinction in whether the control shell is flat.

Given the nature of the NICU, treatment is often performed by opening the hand port for quick access, and the shape of the locking mechanism differs between the two designs as well. Table 17

presents the usability evaluation results and design improvements for these two designs.

In the fourth formative evaluation, usability issues were identified across several components, including an oversized hand port, complex physical buttons on the monitor, and an insufficient number of sensor cables. Notably, user requirements for drawers have been a frequent request since the initial stages, and due to the NICU's high demand for various medical devices and items for patient care, the size and configuration of the drawer are classified as key considerations.

Table 17. Feedback and Improvement from the 4th Formative Evaluation

Category	Feedback	Improvement
Handport Shape	• The hand port is too large, making it difficult to use when opened for patient treatment	• Reduce the size of the hand port
Drawer	• When configured in two tiers, the interior of the upper compartment is fully partitioned, making it inconvenient to store items	• Keep the two-tier structure, but make the partition removable or redesign it as a single compartment
Mattress Rotation	• The mattress rotates 180 degrees and has a handle, which reduces the risk of it falling	• Maintain the design(rotating x)
Column Back	• The monitor arm may protrude and catch on the wall if used close to the wall	• Adjust the monitor arm to allow free movement when rotating
Monitor	• Currently, the knob is located at the top, making it challenging for shorter nurses to use	• Move knobs and buttons to the bottom • Change the monitor handle size and thickness • Position the monitor alarm at the top for easy visibility
Sensor Cable	• Accessibility is limited as it is only on one side	• Address accessibility issues by increasing the number of ports
Caster Lock	• The symbol is not intuitive in meaning	• Since the caster lock is unlikely to be used frequently, this function has been removed

After the fifth formative evaluation, the design was revised, and the 6th and 7th formative evaluations were conducted. The process for the 6th and 7th formative evaluations is shown in Figure 27. In the 6th formative evaluation, an additional usability assessment was conducted for each component of the incubator using 3D images.

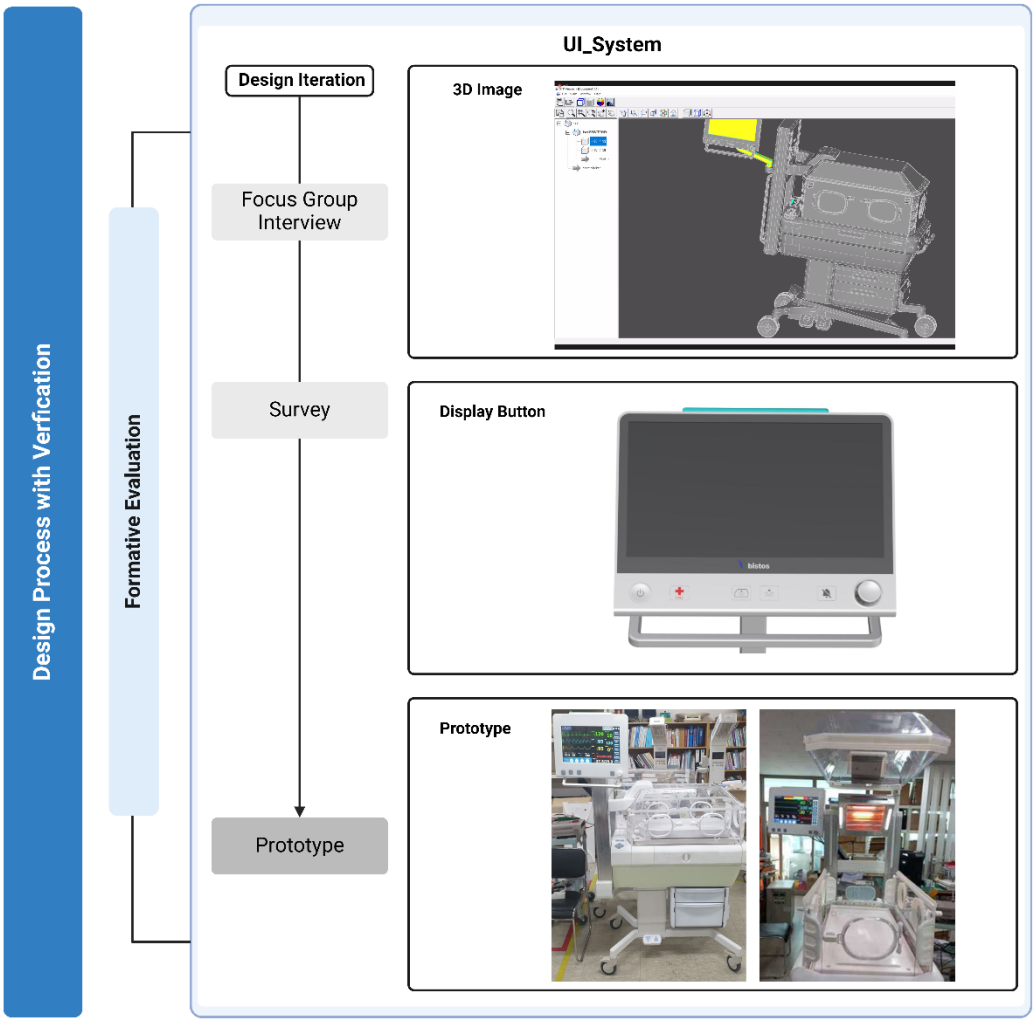


Figure 27. UI Enhancements Through the 6th and 7th Formative Evaluations

Two NICU medical staff and three usability experts gathered to conduct the 6th formative evaluation, a focus group interview, on the 3D draft shown in Figure 27. In this evaluation, feedback was gathered on the arrangement order of each parameter for the sensor connection connector. Currently, the connectors for weight, vibrator, and phototherapy sensors are positioned at the top, while the cables for monitoring the patient's vital signs are connected at the bottom. However, because the ECG and SpO_2 cables must be connected directly to the patient, it was necessary to relocate the sensor connection area to the top, closer to the patient, which was subsequently incorporated into the design.

Additionally, as part of the graphical user interface development, a 7th formative evaluation survey was conducted with 10 NICU medical staff, focusing on the physical buttons located at the bottom of the incubator's display. The survey covered button placement order, color, shape, and the presence of any unnecessary buttons. Table 18 presents the survey results regarding the physical buttons at the bottom of the display.

Table 18. Display Bottom Button Survey Results

Category	Feedback	Improvement
Layout	• Power - Nurse Call - Internal Lighting - Warming Device Lighting - Alarm Pause - Knob	• Power - Internal Lighting - Warmer Lighting - Alarm Pause - Change to Knob
Color	• Power On (green), Power Off (red) • Nurse Call remains red • Alarm Pause button displays colors such as red, orange, and yellow	• Change power button color • When the Alarm Pause button is pressed, it changes to red
Shape	• The light icon for the warmer is not intuitive	• The warmer icon changes to a column shape
etc	• Phototherapy ON/OFF button needs to be added	• Power - Internal Light - Warmer Light - Phototherapy - Alarm Pause - Change to Knob

Initially, a usability evaluation was conducted with 10 medical staff, revealing that the Nurse Call button is not used in the NICU. This button is generally unnecessary since nurses are stationed 24 hours a day and due to the nature of newborn care, the Nurse Call button cannot be pressed by patients. Consequently, this function was removed during design improvements. Additionally, feedback indicated inconsistencies in color and shape preferences. Such inconsistencies in commonly used colors and icons can lead to incorrect operation. To address this, the colors and icons of the physical buttons were revised as shown in Table 18.

The final prototype was developed following seven usability evaluations focused on the system's user interface. Usability evaluations were conducted iteratively, starting with the external structure of the incubator and progressively narrowing the scope to specific detailed components. This approach enabled continuous integration of user feedback and improvements across all stages. From a system perspective, when integrating the incubator with a patient monitoring device, substantial improvements were made to the user interface, including optimizing the monitor's size and placement as well as enhancing the overall appearance of the converged incubator.

2) Graphical User Interface Design Iteration

To develop a graphical user interface for the display to be installed in the incubator, functional analysis of similar products was conducted. At the idea design sketch stage, the screen was divided into sections, and a layout for each item was created, as shown in Figure 28.

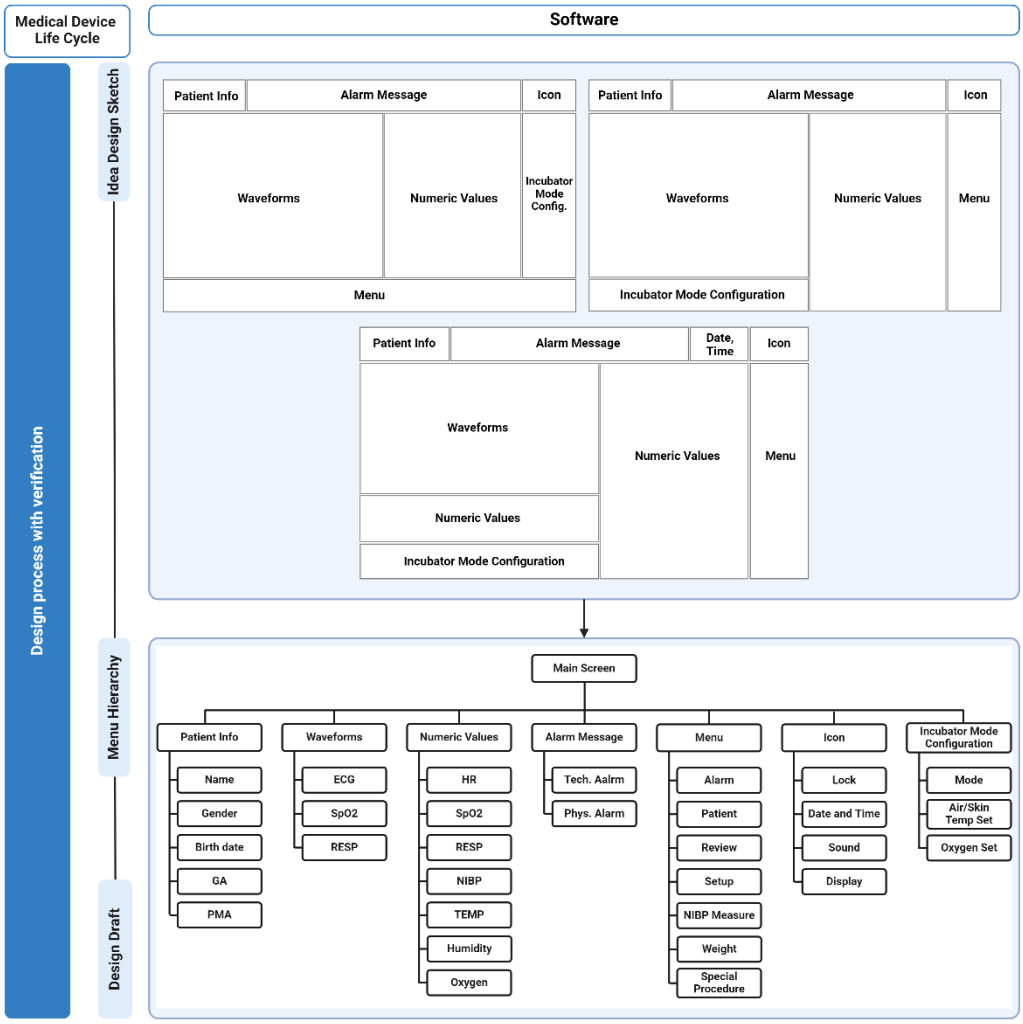


Figure 28. GUI Layout and Menu Hierarchy Design

Through device comparison and functional analysis, the necessary functions for a multi-functional incubator were identified, and a menu tree was developed, as shown in Figure 28. This menu tree includes sections for mode changes typically found in incubators and parameter checks for body weight, oxygen, and humidity, in addition to the essential functions of traditional patient monitoring devices: patient registration, alarm message window, waveform and parameter area, and menu button. Subsequently, approximately 350 screens were created using Adobe XD, a prototyping tool, as shown in Figure 29.

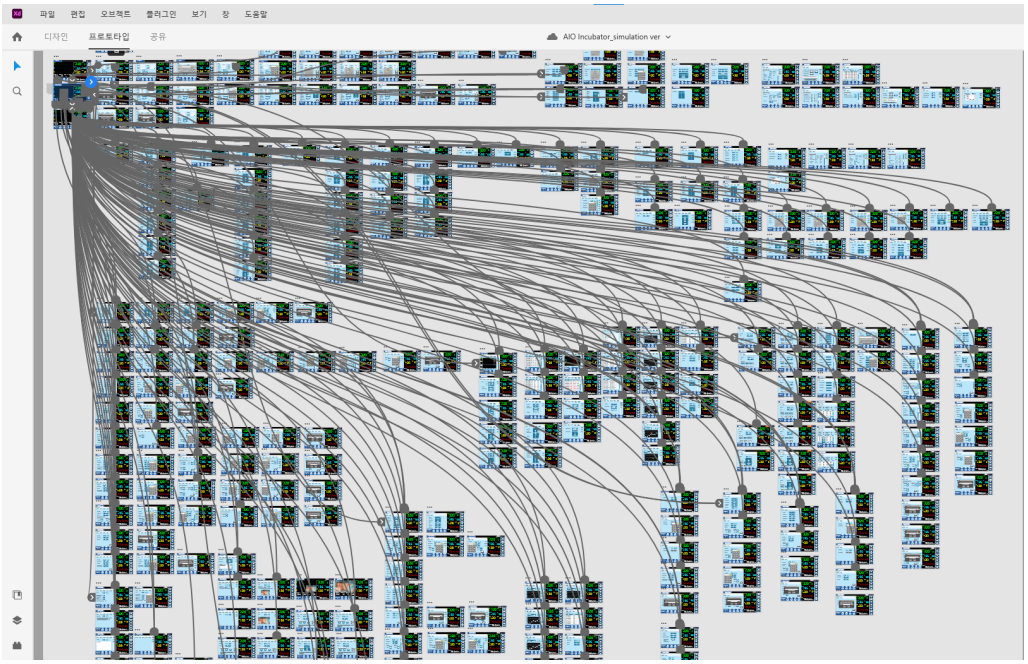


Figure 29. GUI Design with Adobe XD

When developing a graphical user interface, ANSI/AAMI HE 75:2009(R2018) and IEC 60601-1-8 standards were referenced to ensure user-centered design, minimize use errors, and comply with regulations. As shown in Table 19, these standards guided layout, button design, font size, color composition, alarm indications, and other elements [39].

Table 19. Guidelines for Graphical User Interface Design[39]

Category			Meaning
Color	White	• conventional practice	• primary information on a black background
	Red	• Alarm condition	• High priority
		• Hazard	• Danger(an associated hazard will be deadly or will cause property damage)
		• Conventional practice	• Arterial blood pressure • OFF, power OFF • Stop, emergency stop, Fault condition
		• Association	• Warm, hot
	Yellow	• Alarm condition	• Medium or low priority
		• Hazard	• Caution (an associated hazard could be injurious or cause property damage)
		• Conventional practice	• Pulmonary blood pressure
		• Association	• Warm
	Green	• Conventional practice	• ON, power ON • Go or continue • All OK • Ready (available for use)
	Cyan	• Alarm condition	• Low priority
	Black	• Conventional practice	• Primary information on a white background
		• Waveform color	• white and light-colored waveforms drawn on a black background
Touch screen interface		• Activation states	• Differentiation from the previous state when activated • Preference for three-dimensionality
		• Target size	• Enlarged touch area • Minimum target size of 1.5 cm (0.6 inches)
		• Target spacing	• 2cm (0.8 inches) target center distance on the touch screen
		• Scrolling	• Arrow keys convenience over slider bar

The graphic user interface design process, which was refined through eight formative evaluations, is shown in Figure 30.

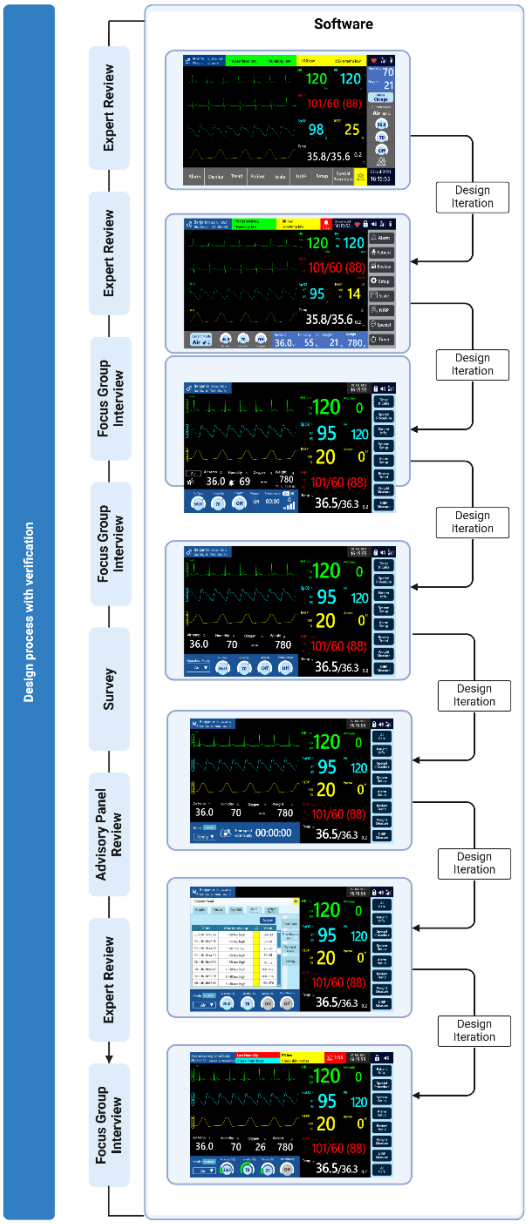


Figure 30. GUI Design Iteration Process

In the first and second formative evaluations, three usability experts conducted an expert review to discuss the functions to be included across seven areas and evaluated the initially designed graphical user interface. Based on a survey of similar equipment, the patient monitoring device menu was positioned at the bottom, and the incubator menu was placed on the right. Using this layout, a graphical user interface was designed with two concepts, and the usability experts gathered to conduct a usability evaluation. The feedback from usability experts is presented in Table 20 below.

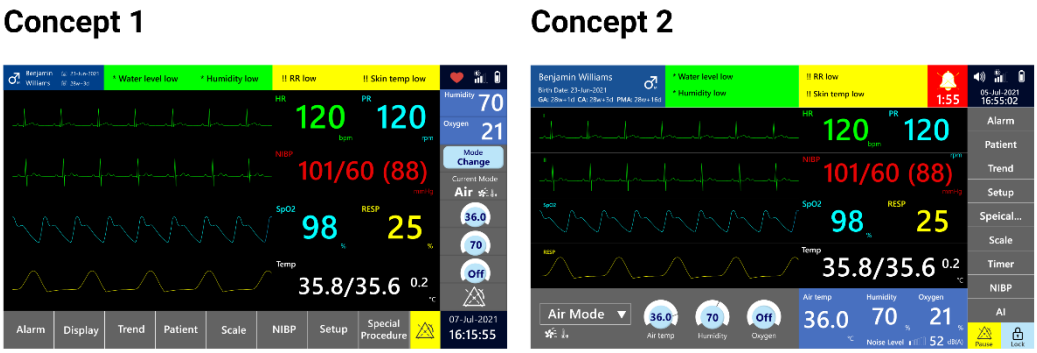


Figure 31. Initial Concept Illustration of the GUI

Table 20. Usability Results of the GUI Based on Expert Review

Category	Feedback	Improvement
Concept 1	• There are two alarm pause buttons, which reduces space utilization	• The alarm pause button has been removed from the bottom menu
Concept 2	• The incubator settings area is too large, reducing the visibility of waveforms and numeric values • The patient information display is too large, and the alarm message area takes up excessive space	• The design was modified to enhance the visibility of waveforms and numeric values by adjusting the incubator mode and reducing the size of the patient information display area

For the third formative evaluation, two NICU medical staff and three usability experts gathered to conduct a focus group interview. In this evaluation, feedback was collected for each item on six draft graphical user interfaces. As shown in Figure 32, the drafts are divided into two types based on the location of the menu button: Concepts 1, 2, and 3 have the menu located at the bottom, while Concepts 4, 5, and 6 have the menu button positioned on the right.

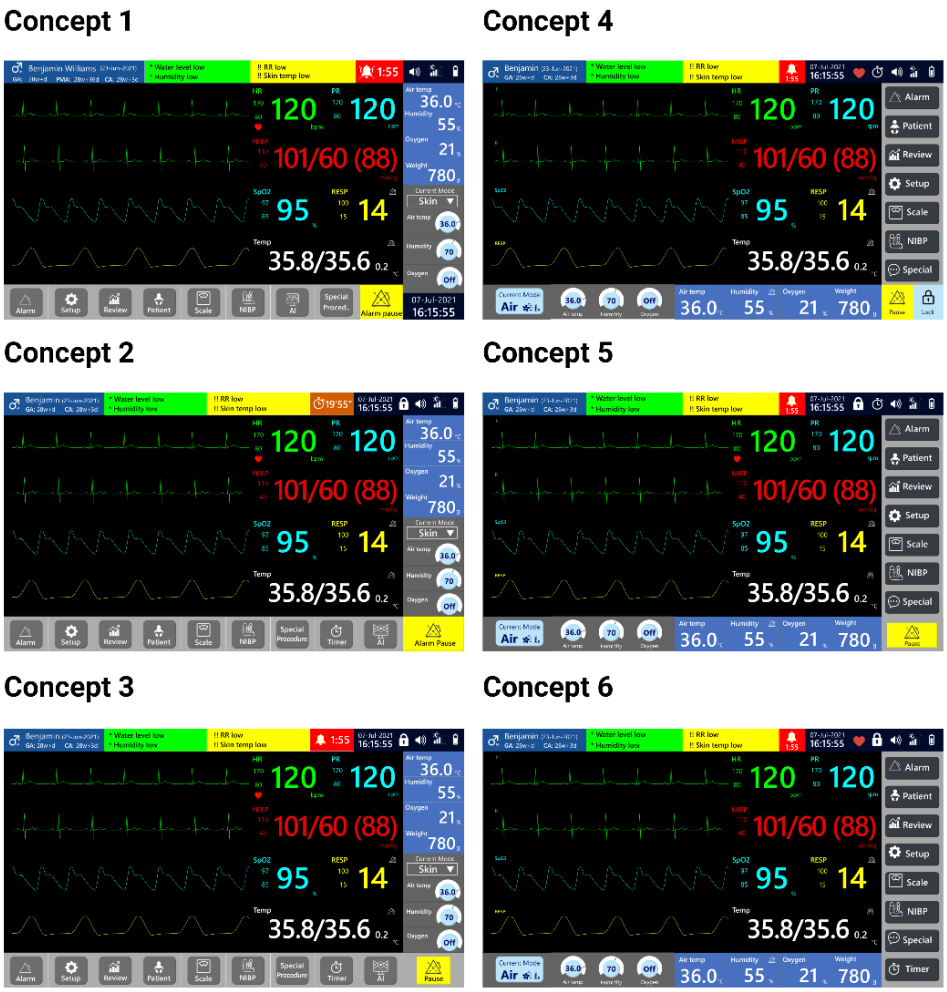


Figure 32. GUI Reflecting the Results of the 1st, 2nd Formative Evaluations

NICU medical staff and usability experts most preferred Concept 6, as it offered a clear distinction between each area and provided the best visibility. The results are shown in Table 21. The graphical user interface reflecting the three design improvements is shown in Figure 33.

Table 21. Feedback and Improvement based on the 3rd Formative Evaluation

Category	Feedback	Improvement
Patient Info	• GA and PMA are included; CA is not required.	• Only GA and PMA are displayed, excluding CA.
Numeric Values	• Numeric values must be displayed in a large size, with HR and SpO_2 shown prominently • Waveform and numeric values should be displayed in the same location • For PR, it would be better to display it in a smaller size under SpO_2	• The width of the menu button was reduced, and the numeric value area was expanded to make the numbers appear larger • The design was adjusted to align the waveform and parameters on the left and right sides, and for ECG, it was modified to a single LEAD display
Icon	• Displaying Pacemaker in the icon area seems unnecessary	• The Pacemaker design was changed to be included within the HR numeric value area

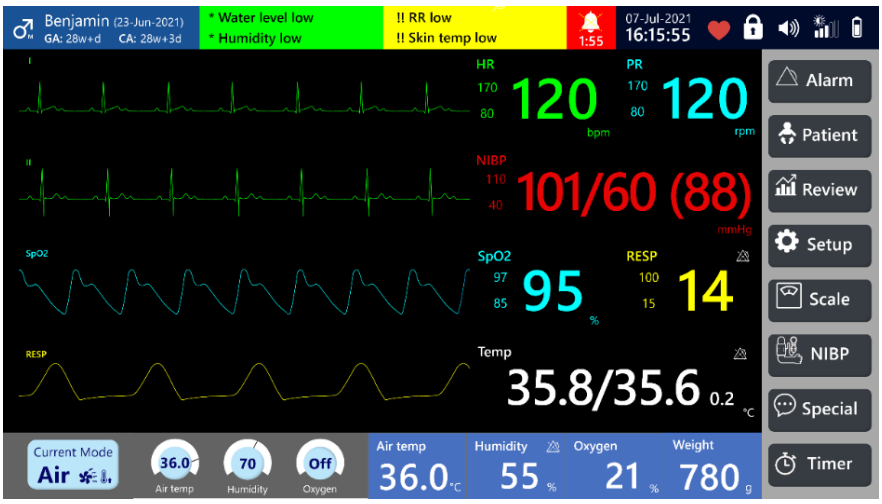


Figure 33. GUI Reflecting Feedback from the 3rd Formative Evaluation

According to the alarm priority levels specified in ANSI/AAMI HE 75:2009(R2018), the colors were changed in the updated design to red for high-priority alerts, yellow for medium-priority alarms, and cyan for low-priority alarms. Furthermore, each waveform's and numeric value's places were matched, and the numeric values' sizes were adjusted. Additional information included in the design after Figure 33 is shown in Table 22.

Table 22. Pre- and Post-Improvement Comparison after the 3rd Formative Evaluation

Category	Prior to Improvement	Following Improvement
Menu button	• Display icons in gray	• Change font color to light blue
Alarm	• Red(High), Mid(Yellow), Low(Green)	• Red(High), Mid(Yellow), Low(Cyan)
Numeric value	• Same as the waveform area	• Expand numeric value area
Incubator mode	• Positioned at the bottom of the main screen	• Positioned at the bottom left of the main screen • Added icons for phototherapy and warmer

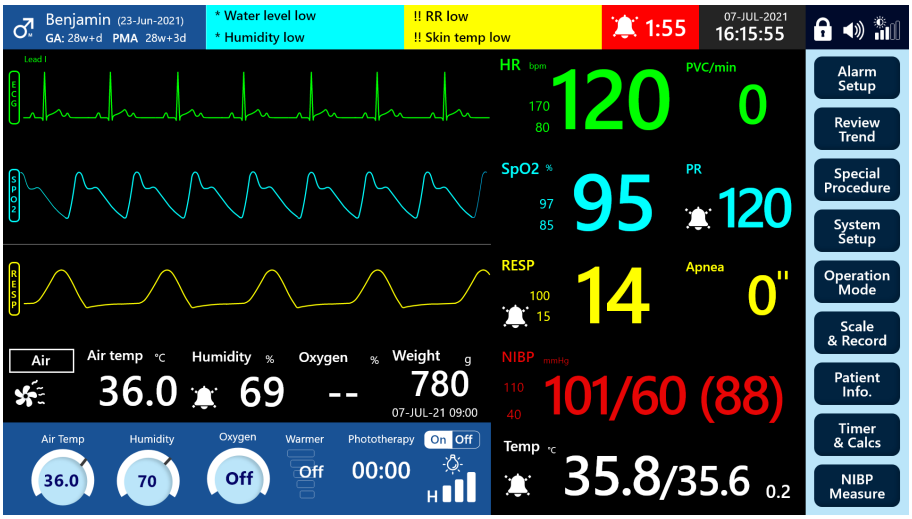


Figure 34. GUI Improved Through the 3rd Formative Evaluation

In the fourth formative evaluation, two NICU medical staff members and three usability experts convened to conduct a usability evaluation through a focus group interview, focusing on the graphical user interface of the prototype. This prototype, designed to enable screen simulation, was created using Adobe XD. Table 23 presents the insights and design improvement directions that emerged from the focus group interview.

Table 23. Feedback and Improvement Based on the 4th Formative Evaluation

Category	Feedback	Improvement
Phototherapy	• There is no need to adjust the intensity, and the on/off button appears to have high visibility	• Improved design with phototherapy on/off button on the main screen
Warmer	• There is no need to adjust the intensity, and the on/off button appears to have high visibility	• Added a button to switch to warmer mode in the incubator
Menu	• To improve usability, frequently used buttons should be placed at the bottom of the menu, such as weight measurement and NIBP (non-invasive blood pressure) measurement	• Reordered the NIBP measurement and weight measurement buttons at the bottom of the menu

. In the fifth formative evaluation, a usability assessment was conducted on the display attached to the incubator. This evaluation involved seven NICU medical staff members who interacted with a graphical user interface (GUI) designed in Adobe XD and participated in a survey. The System Usability Scale (SUS) was used to assess satisfaction with each screen layout as well as overall system satisfaction. The participating NICU medical staff members had more than three years of experience and at least one year of experience using incubators from GE and DRÄGER, as well as patient monitoring systems from GE, PHILIPS, and DRÄGER.

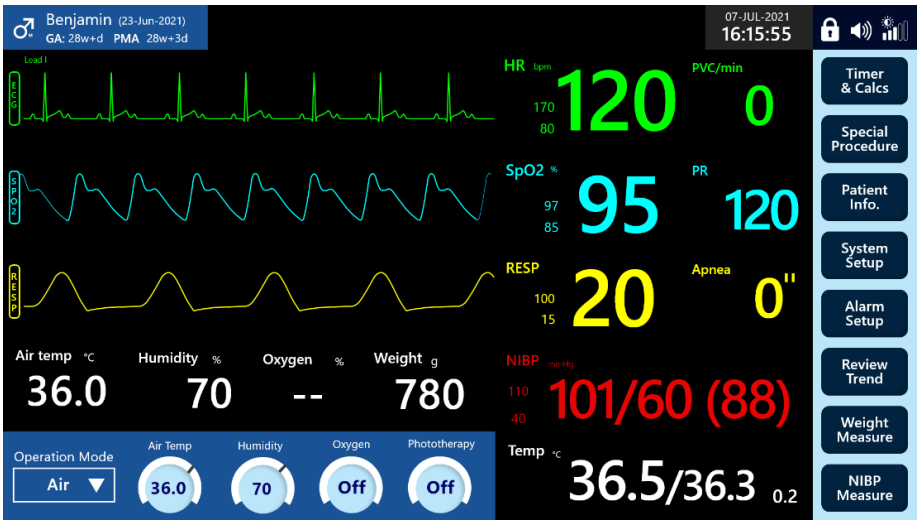


Figure 35. GUI Improved Through the 4th Formative Evaluation

As a result of this usability evaluation (survey), it was confirmed that the most frequently used functions in the NICU are Alarm Pause and NIBP Measurement, both of which are utilized more than three times per day. Regarding satisfaction with the graphical user interface, the overall average score was 3.8, with the highest score being 4.1 for the menu button in the patient information section, and the lowest score being 3.1 for the ease of use of the timer and calculator functions. It is believed that the low score for the calculator function's ease of use may be due to the NICU medical staff rarely using this function during evaluation. Satisfaction scores and feedback for each item are presented in Tables 24 and 25. Furthermore, according to the SUS results, an average score of 68 or higher indicates that the system is considered usable. However, in this formative evaluation, the average SUS score was 61.14, below the threshold of 68, suggesting that overall system improvements are needed. [26, 36, 37].

Table 24. GUI Satisfaction and Feedback from the 5th Formative Evaluation

Category	Mean±SD	Feedback
Main Screen	3.8±0.74	• Font size should vary depending on importance. • The font color for NIBP needs to be changed • The order of menu button placement should be adjusted
Alarm Indication	3.6±0.75	• It is necessary to make the monitor LED and the background color of the parameter area blink
Patient Info	3.9±0.72	• Instead of using gender symbols, "F/M" should be displayed in larger letters • Blood type should be displayed as RH (+/-)
System setup	3.7±0.90	• Default values are important.
Alarm setup	3.8±0.89	• If a default value is set, it should be maintained regardless of whether the device is powered on or off
Review	3.8±0.93	• For table review, it would be helpful to allow searches by time zone • When reviewing alarm messages, all vital sign values other than those associated with the message should be displayed
Incubator Mode	4.0±0.85	• The mode name should be changed (from "Mommy Mode" to "Kangaroo Mode")
Weight	3.8±0.82	• Zeroing should be easy to perform
NIBP Measure	4.0±0.76	• It would be useful to view only BP measurement values at once
Warmer	3.6±0.83	-
Familyship	3.9±0.90	• When viewing a patient via camera, it would be beneficial if the patient appeared larger in the waveform area • It would be helpful if the angle could be adjusted and the position changed
Phototherapy	3.7±0.77	• There is no need for minutes or seconds; setting time in hours would be better
Timer, Calculation	3.3±0.76	• The drug calculator is not a frequently used function
Icon	3.7±0.95	-

Table 25. Design Improvements Reflecting Feedback from Survey

Category	Foreseeable Use Error	Improvement
Main Screen	• The order of the menu buttons is not based on frequency of use, which causes delays in accessing the menu and can hinder the treatment process	• Adjustments to menu button placement order after further consultation, e.g., (Top) Patient Info / Setup / Timer / Review / Weight Measure / NIBP Measure (Bottom)
Alarm Indication	• Due to the nature of the NICU, where there are numerous medical devices and frequent emergency situations, merely flashing the alarm message window may not be sufficient to draw attention, potentially delaying patient treatment • Noise issues arise because the alarm cannot be cleared when the touch function is locked or due to a touch error in the software	• Modified design with blinking monitor LED and parameter area (background color switching) • Placed the auditory alarm release button as a physical button at the bottom of the control panel (monitor)
Patient Info	• Entering patient information requires a considerable amount of data, leading to extended patient registration times • Blood type is not accurately categorized as RH, which prevents accurate retrieval of patient information	• To distinguish between necessary and optional input fields, place an asterisk (*) before the input information label • Added a checkbox for RH blood type
Alarm Setup	• Since the incubator is cleaned periodically, resetting it each time the power is turned on results in delays before patient admission, potentially hindering timely treatment	• Designed to allow creation and saving of preferred alarm settings for each hospital or unit as a preset, or to set alarm-related default values by entering a specific code to access management mode

Category	Foreseeable Use Error	Improvement
Review	• Scrolling by touch rather than with a mouse is inconvenient, and events are hard to review quickly, making it difficult to check them in a timely manner	• When shifting the graph left or right, it can now be moved with a rotary knob in addition to touch scrolling • Event review for physiological alarms is designed to display all biosignal values, not just those related to the alarm message
Incubator Mode	• Since it does not follow the standard Kangaroo mode, finding the menu takes extra time	• Changed "Mammy Mode" to "Kangaroo Mode."
Weight	• In the NICU, zero adjustment is frequently used when measuring weight, but the process requires multiple steps (System setup → Module → Weight → Weight calibration), resulting in delays in measuring the patient's weight and, consequently, in the treatment process	• Added a zero-point adjustment button in the menu window that appears when selecting the weight parameter area
Familyship	• The camera function is hard to locate, and the inability to quickly check the patient's condition further delays the process	• Set the display of patient images across the entire waveform as the default, with an option to change the display method
Timer, Calculation	• This function is rarely used, yet additional menus that don't need to be on the main screen are currently there, making the screen cluttered and other tasks more difficult to perform	• Removed the calculator function or moved it to a submenu within the Special Procedures menu, instead of placing it as a Menu button on the main screen

Based on the feedback obtained from the fifth formative evaluation, an advisory panel review was conducted in the sixth formative evaluation with two NICU medical staff members. The evaluation results are presented in Table 26.

Table 26. Feedback of Advisory Panel Review

Category	Prior to Improvement	Following Improvement
Incubator Mode	• Mammy mode	• Family mode
Canopy Operation Method	• Operation of Canopy Opening and Closing Method on the Display	• Operation of Canopy Opening and Closing Method Using the Display and External Physical Buttons
External Temperature and Humidity Display of the Incubator	• Main Screen Display	• Menu Button Entry and Submenu Check

"Kangaroo Mode," the name displayed on the graphical user interface during kangaroo care in the NICU, where premature infants interact with their parents through direct skin-to-skin contact, is a patented term of Dräger, making it difficult to use. Feedback was gathered on alternative names such as "Mommy Mode" or "Family Mode." As a result, "Family Mode" was chosen to reflect the preferences of NICU medical staff. Additionally, the inclusion of a "Familyship" menu within the incubator interface improved term consistency.

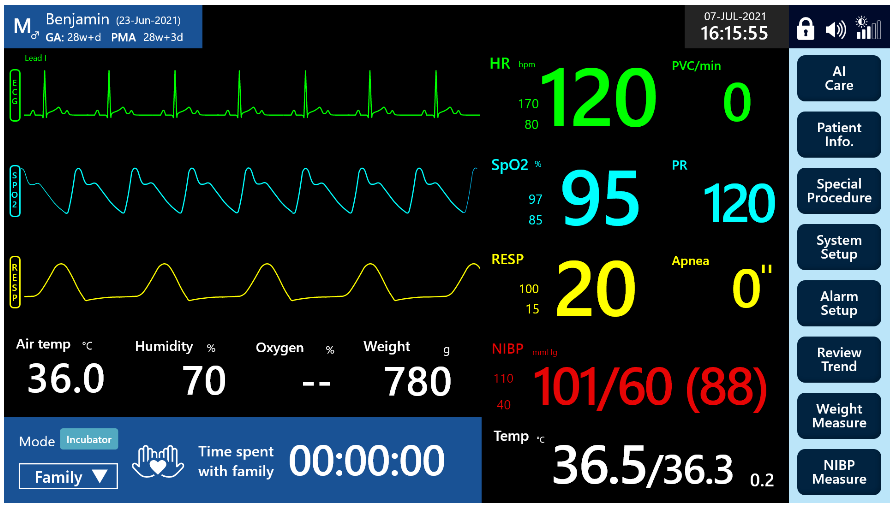


Figure 36. GUI Modification for Incubator Mode Settings in Family Mode

Additionally, there was feedback suggesting that a software error could potentially prevent the opening and closing of the canopy. Given the nature of the incubator, where the patient is inside, both physical and software buttons were used to control the canopy operation. For the external temperature and humidity of the incubator, the menu was configured so that these parameters could be viewed on a detailed screen rather than on the main screen.

In the seventh formative evaluation, three usability experts discussed the default value settings, which remain unchanged even when the monitor is turned off and back on, as identified in the fifth formative evaluation. A feature to export or import hospital settings was added to the menu structure. Furthermore, in the review of alarm trends, adding color to indicate alarm priority was discussed to enable quicker identification of alarm levels. In the previous version, risk levels were indicated solely by a symbol (!), but in the revised design, the graphical user interface was improved to display alarm trends by risk level using both the symbol (!) and color coding.

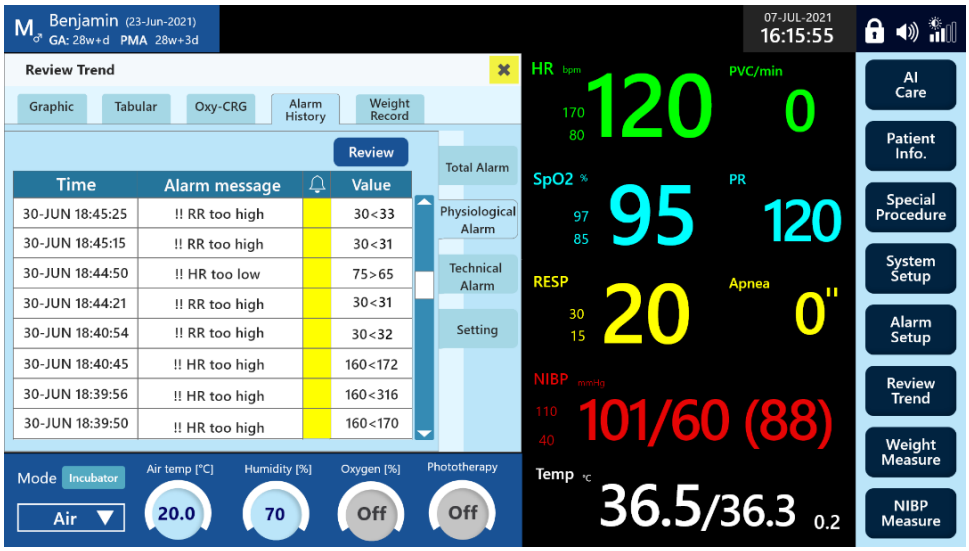


Figure 37. GUI Reflecting Feedback from the 7th Formative Evaluation

In the eighth formative evaluation, the graphical user interface was assessed on a 15-inch LCD, similar in size to the display attached to the incubator, through a focus group interview with two NICU medical staff members and three usability experts. Table 27 presents the usability issues and potential use errors identified in each area.

Table 27. Usability Concerns and Use Errors Observed in the 8th Formative Evaluation

Category	Usability issues identified	Foreseeable Use Error
Main screen	• The patient's name is cut off in the patient information area, making it difficult to identify the patient • It would be helpful if the alarm message were displayed more clearly • The font size of the alarm message is too small • Visibility of numeric data is reduced	• It is difficult to identify which mother the patient is associated with • When an alarm sounds, there is a delay in treatment due to slow recognition of the alarm • Numeric data values may be difficult to see
Patient Registration	• It is inconvenient that a patient can only be registered after all values are entered • The space to enter the patient's name and ID is too limited, making registration difficult	• Patient registration is urgently needed, but all fields must be completed to register, causing delays in the patient's treatment • The patient's name is truncated, increasing the risk of incorrect entry
System Settings	• Adding a "Default" button to all windows would be beneficial. • Including an "Admit Time" in User Maintenance - Time would be helpful • The term "volume" is unfamiliar	• If the setting values fluctuate frequently and there is no reset button, it is difficult to revert to the previous value • Unable to confirm when the patient was admitted

Category	Usability issues identified	Foreseeable Use Error
Parameters Settings	• The interface is divided into Parameter and Alarm tabs, but there is no "Default" button in Parameter tab • In the arrhythmia section, Bradycardia and Tachycardia are frequently used parameters but are hard to find as they are located at the bottom of the page • In the Weight menu, it would be helpful to compare the patient's current weight with their admission weight and to link the weight information from the incubator to the EMR • Displaying the patient's current weight with a range of +/- 300~350g would be beneficial	• It needs to be reset to the previous value, but since it is listed lower down, it takes time and the reset is not completed quickly • I need to check alarms for frequently used items, but they cannot be checked quickly
Weight Measurement	• It would be useful to prompt whether zero-point adjustment should be performed when measuring weight	• If weight is measured without zero adjustment, an inaccurate weight may be recorded
NIBP Measurement	• If a measurement error occurs, it would be helpful to display a window asking if you would like to measure again	• If a measurement error occurs, the erroneous value may still display
etc.	• The "Default" button needs to be quickly accessible during tasks, so its visibility is important • The scroll bar is too long, making it difficult to use • For list boxes, it would be beneficial to standardize their arrangement, either at the top or bottom	• Failure to press the reset button quickly may delay adjustments to default settings or alarm limit values • Excessive scrolling delays the process of checking and addressing items

Figure 38 shows the graphical user interface design improved through the eighth formative evaluation. The top screen in Figure 38 is the main screen, representing the interface of the

converged incubator. This screen integrates the patient monitoring device's vital signs with parameters for controlling the patient's temperature in the incubator and warmer. Similar to the layout of existing patient monitoring devices, waveforms are displayed on the left and numerical values on the right. Given the nature of the NICU, where frequent weight measurements are required, the patient's weight can be displayed on the main screen to allow continuous monitoring.

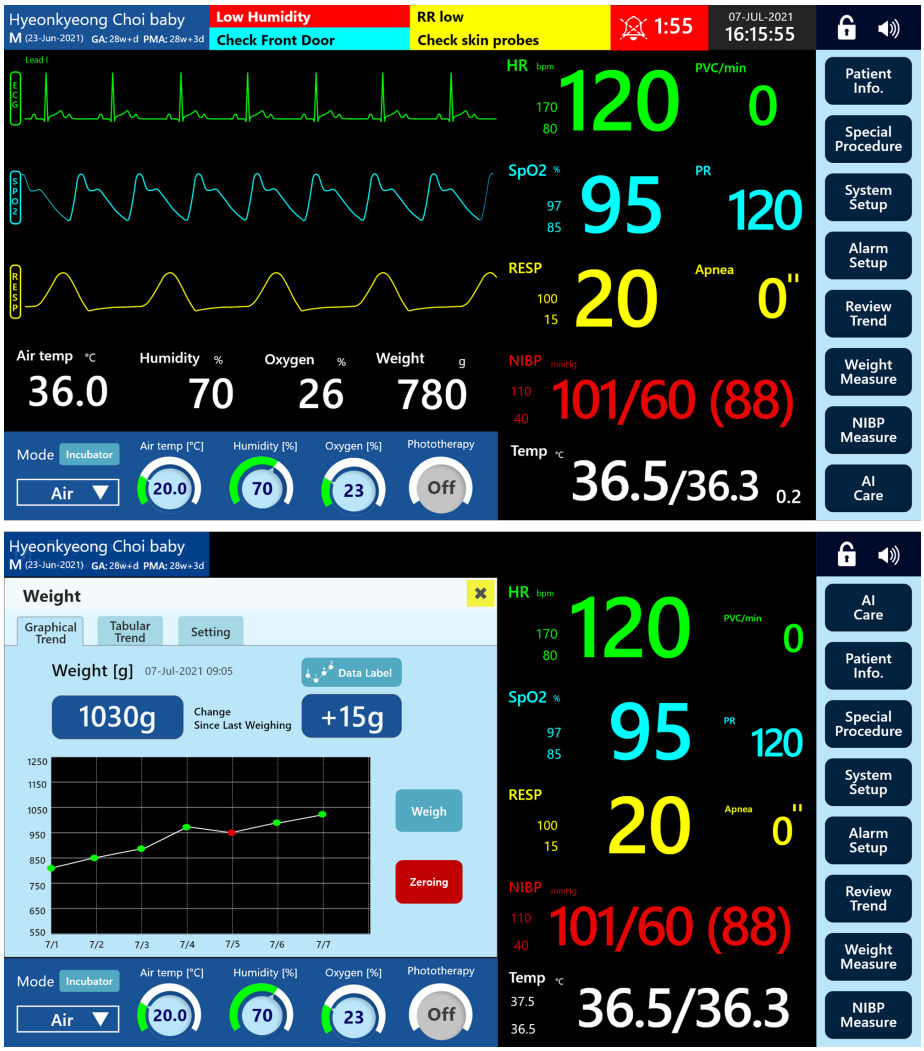


Figure 38. GUI Reflecting Feedback from the 8th Formative Evaluation

3.1.4 Validation of Final User Interface and Graphical User Interface

Figures 39, 40, and 41 show the converged neonatal incubator with a design improved after 15 formative evaluations were conducted for each system and software in the 'Design Process with Verification' stage. Figure 40 shows the final design when operating in Incubator Mode and Warmer Mode. Figure 41 shows the final design in Phototherapy Mode and Surgical Mode.

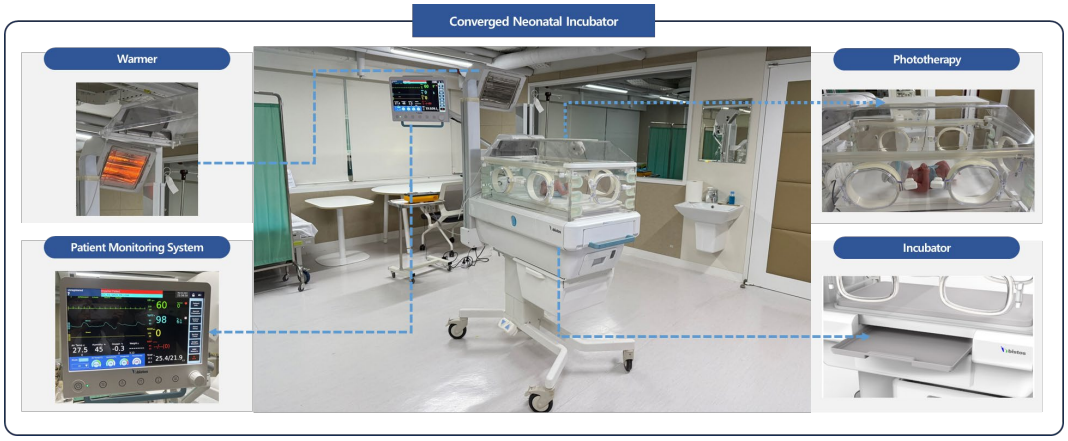


Figure 39. Converged Neonatal Incubator

Figure 40. Final Design of Incubator and Warmer Modes

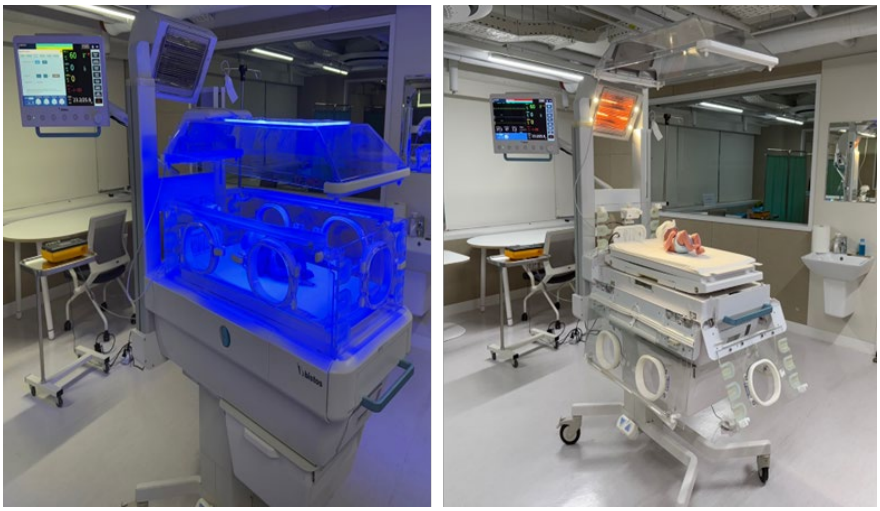


Figure 41. Final Design of Phototherapy and Surgical Modes

To confirm the final user requirements for the incubator that integrates the improved design of the warmer, phototherapy, and patient monitoring system, a usability test was conducted on the fully integrated system and software. The suitability for use was evaluated based on a use scenario that considered hazards, involving 15 NICU medical staff. Table 28 presents the scenarios developed through task analysis and hazard analysis of similar devices.

Table 28. Simulated-use Tasks for Summative Evaluation

Scenario	NO.	Task
Check the User Manual.	1	• Check the safety information (precautions for incubators and warming devices) in the user manual.
	2	• Review the symbols in the user manual.
System Operation	3	• Lock the wheels of the incubator.
	4	• Turn on the device.
	5	• Connect the cable.
	6	• Set the operating mode on the control panel.
	7	• Adjust the height of the incubator stand.

Scenario	NO.	Task
	8	• Lock the screen.
Patient Arrangement	9	• Adjust the zero point for weight measurement before placing the patient.
	10	• Open the side door.
	11	• Place the newborn dummy on the mattress.
	12	• Lock the side door using the lock.
Patient Registration	13	• Register the patient.
Weight Measurement	14	• Measure the patient's weight.
	15	• Check the patient's weight trend.
	16	• Display and check the patient's weight data label.
Monitoring and Adjustment	17	• Check if there is water in the humidity container.
	18	• Set humidity to 60%.
	19	• Adjust the ECG waveform size and speed.
	20	• Turn the Pacemaker setting to "On."
	21	• Adjust alarm limits for SpO_2.
	22	• Measure the NIBP.
Surgery Progress	23	• Open the side door and prepare for surgery.
	24	• Turn on the surgical light.
	25	• After surgery, lock the side door using the lock.
Activate Warmer Mode	26	• Switch the mode from Incubator Mode to Warmer Mode.
	27	• Check the patient's temperature in Warmer Mode.
	28	• Switch from Warmer Mode back to Incubator Mode.
Trend Reviews	29	• Open the trend review window.
	30	• Access the alarm message list window.
Change Patient Position	31	• Move the mattress left and right to change the patient's position.
	32	• Return the patient to the original mattress position.
	33	• Check the patient's movements using the camera.
	34	• Open the access door to check on the patient.

Scenario	NO.	Task
Phototherapy	35	• Turn on phototherapy.
	36	• Set the phototherapy duration to 1 minute.
	37	• Turn off phototherapy.
Patient Discharge	38	• Discharge the patient.
Device Power	39	• Turn off the device.

Two distinct rooms—an evaluation room and an observation room—were used for the usability test. Based on an investigation of the anticipated use environment during the 'User Needs' stage, the evaluation room replicated a NICU-like setting. Medical staff with at least a year's experience working in the NICU and familiarity with both incubators and patient monitoring systems were eligible to take part in the usability test. The participants' NICU work experience ranged from 2 to 16 years, with an average of about 6.93 years.

During the usability test, the average task success rate was 95.90%, as shown in Figure 40. Task 24, which involved turning on the surgical light, had the lowest task success rate. However, since surgical lights are not currently used in the NICU, participants lacked familiarity with operating them on the evaluation device. Many participants expressed that they could use it effectively in the future as training and experience increase.

Given the features of medical devices that incorporate patient monitoring capabilities, tasks connected to monitoring (Tasks 17 to 22) had a 100% success rate, confirming their appropriateness for use. While tasks requiring phototherapy, which is typically utilized as a separate device in clinical practice (Tasks 35 to 37), also showed a high success rate of 97.78%, so did tasks related to the warmer (Tasks 26 to 28).

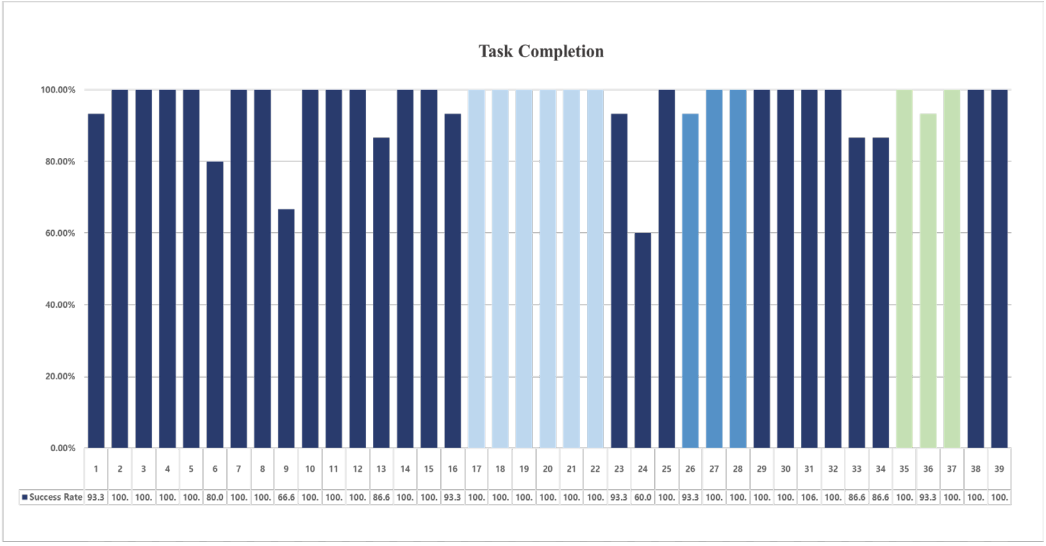


Figure 42. Summative Evaluation Result

Based on the participants' work experiences, the usability test's success rate was examined. The evaluation success rates were compared by splitting the participants into two groups: those with less than 7 years of experience and those with more than 7 years. The overall average work experience was roughly 6.93 years, as seen in Figures 43 and 44. The overall task success percentage for participants with less than 7 years of work experience was 97.44%, whereas the success rate for those with more than 7 years of experience was 94.14%. For tasks 17 through 22, which dealt with patient monitoring systems, both groups completed them with 100% success. Participants with less than 7 years of experience had a 95.83% success rate on activities involving warming devices, but those with more than 7 years of expertise had a 100% success rate. Furthermore, those with less than 7 years of experience demonstrated a 100% success rate for phototherapy-related tasks, while those with more than 7 years had a 95.24% success rate.

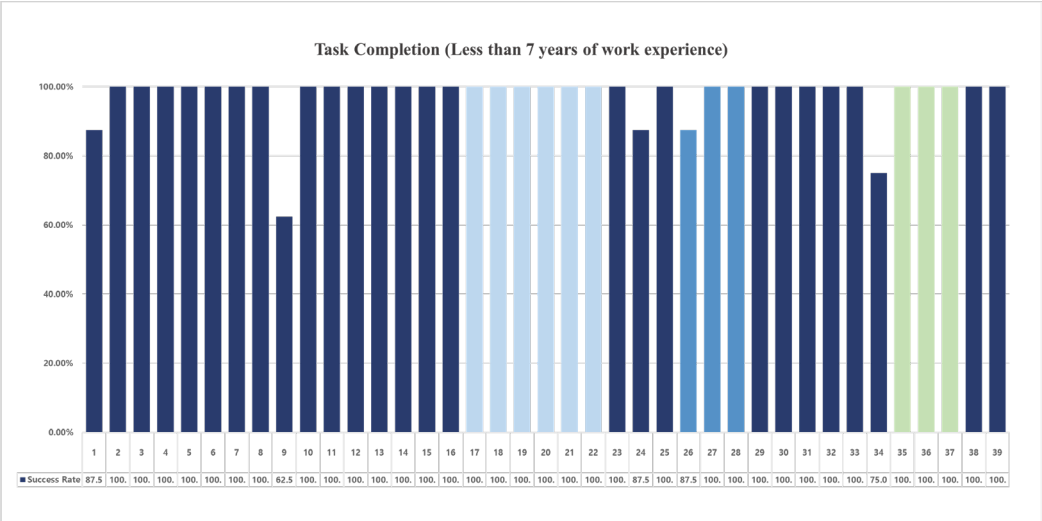


Figure 43. Summative Evaluation Result for Participants with Less Than 7 Years of Experience

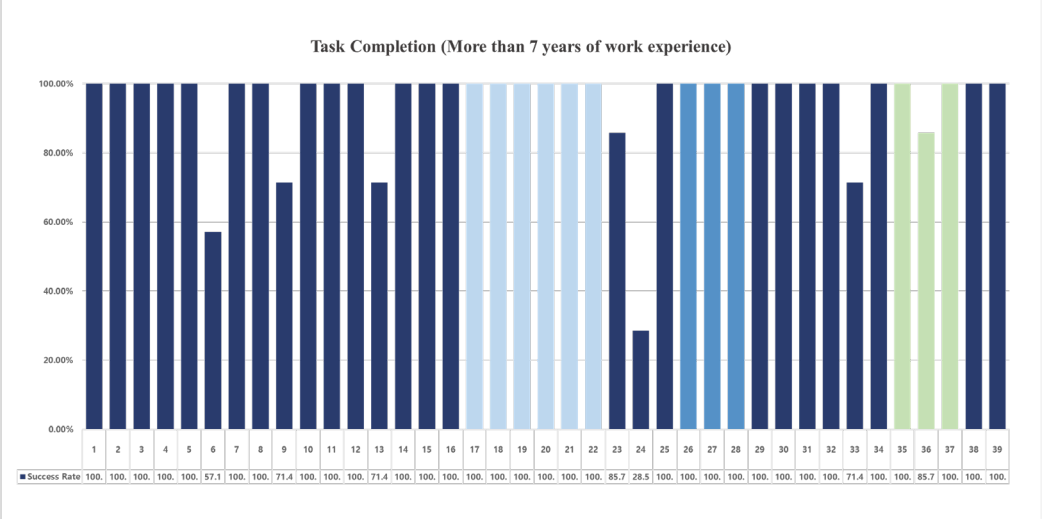


Figure 44. Summative Evaluation Result for Participants with More Than 7 Years of Experience

In comparing the summative evaluation results by work experience, there was minimal difference in the success rate for each component of the converged medical device. However, there was a noticeable difference in the success rate for tasks involving the existing incubator. This difference appeared in tasks related to surgical procedures; specifically, participants with more than 7 years of experience showed the lowest success rate when turning on the surgical light, compared to those with less than 7 years of experience. This result was attributed to participants' familiarity with using a separate operating room light. Feedback from post-evaluation interviews, however, suggested that having a built-in surgical light was useful and that it could be used efficiently with training to acquaint users with its placement.

The final design improved usability even though multiple features were integrated thanks to the test findings, which were carried out with usability in mind from the beginning of development. Through the usability test, it was demonstrated that the NICU treatment process could be streamlined, and the product's quality, safety, and usability could be improved by eliminating the need for a separate patient monitoring device to check the patient's vital signs.

3.2 Converged Medical Device Design Process

When developing medical devices, this study proposes a design process to be considered when designing and developing devices that combine multiple functions, as shown in Figure 45. Figure 45 is a flowchart illustrating the design process of a converged medical device that integrates four distinct functions into a single device. To create a converged medical device, a new process was developed by blending the existing medical device design process, software design process, and usability engineering process.

Five steps make up the current medical device design process: "User Needs," "Design Input," "Design Process," "Design Output," and "Medical Device." Four steps make up the usability process: "User Research," "Analysis," "Design and Formative Evaluation," and "Summative Evaluation." Throughout the medical device design process, verification is carried out from design input to design output.

In addition to usability, quality management (as defined by ISO 13485:2016) and risk management (as defined by ISO 14971:2019) must be considered while designing medical devices. In the design and development of medical devices, potential hazardous situations must be assessed, considering all aspects of the medical device and its operating environment. When designing a product based on risk management that identifies hazards and hazardous situations, it must be developed to minimize risk.

To create a design with high usability, it is essential to incorporate usability considerations into the design process. Four main categories were developed by combining the usability process with the medical device design process and software design process. These four stages are named "User Needs," "Analysis," "Design Process with Verification," and "Medical Device with Validation."

The first step in the medical device design process, software design process, and usability-related process is to determine user requirements, referred to as "User Needs." Although there is no "Analysis" stage in the medical device design process, this step is crucial when designing with usability in mind. The "Analysis" stage proposed in this study includes not only risk analysis within the usability process but also the analysis of devices and functions for design purposes.

The following three steps of the medical device design process "Design Input," "Design Process," and "Design Output" were combined and given the name "Design Process with Verification," which included usability testing at every level.

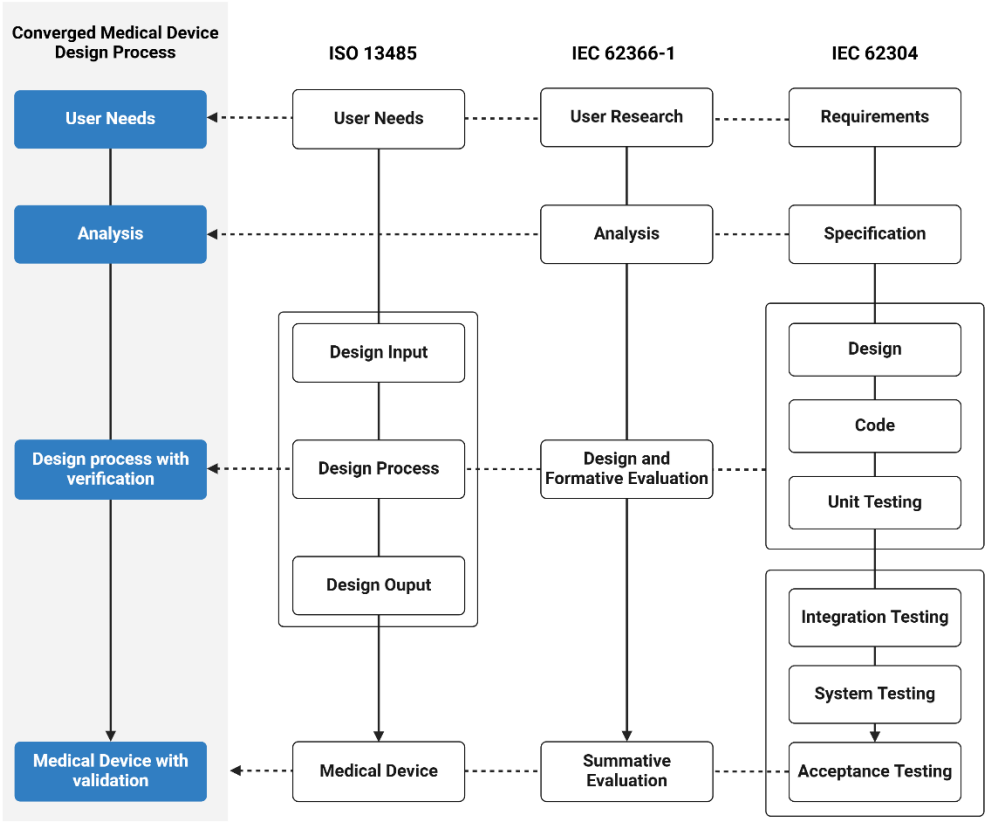


Figure 45. Standards Related to the Converged Medical Device Design Process

The four steps in the "Converged Medical Device Design Process" that this study suggests are described in full below.

1) User Needs

The first stage is the “User Needs” stage. In this phase, it is essential to identify the intended patient population and intended users for medical devices that integrate multiple functions. By determining each patient group and user, the final intended user and patient group can be specified when developing a converged medical device. As multiple functions are combined within a single device, it becomes important to delineate the intended users and patient populations for each individual function. Understanding who the ultimate user of a converged medical device will be is critical for developing a device with high usability.

Subsequently, the use specifications including the use environment, users, and indications of the converged medical device must be established. Once these intended use specifications are confirmed, user requirements must be identified. When developing a converged medical device, all requirements must be derived by synthesizing each user’s requirements into a single, integrated device. This includes investigating areas or requirements for improvement identified while using each separate medical device and assessing whether these requirements align when the products are combined to develop a converged medical device.

Additionally, it is necessary to assess whether any specific requirements exist within the intended use environment for the intended user and to ensure these are incorporated into the device’s development. Notably, for converged medical devices, where various functions are integrated, the devices are likely to be used by a diverse range of users and within multiple environments.

2) Analysis

The second stage is the “Analysis” stage. The initial task within this stage is to conduct a detailed Item and Similar Product Analysis for each medical device function. During the Comparative Analysis phase, similar products should be reviewed using resources such as the Korean Ministry of Food and Drug Safety and the U.S. FDA websites to verify the appearance, functionality, and performance of each product.

After that, a function analysis is carried out, in which the functions of each product are evaluated to see whether features are appropriate for a converged medical device. The patent rights of other companies must be considered and incorporated into the design of medical devices. Additionally, as this process progresses into the design phase, it is essential to identify and document known hazards for similar devices and incorporate potential hazardous situations into the device design.

For risk analysis, known hazards and hazard scenarios are investigated through reports on adverse events, disclosures of safety information, and data on recalled medical devices, utilizing resources such as the Medical Device Safety Bookstore from the Ministry of Food and Drug Safety in Korea. For international cases, the FDA MAUDE database should be consulted to identify known hazards and hazardous situations for similar devices. The results of this risk analysis must be incorporated into the design to ensure that identified risks are addressed and mitigated in the converged medical device.

3) Design Process with Verification

The third stage is the “Design Process with Verification.” In this phase, the design is developed, formative evaluations are conducted, and the design is refined accordingly. During the initial User Needs stage, an idea sketch for a converged product is created, incorporating elements derived from user requirements identified through functional and risk analyses.

When combining multiple medical devices, if the appearance is to be similar to devices A and B, a design is created to reflect the fusion of A and B, followed by a formative evaluation. For devices C and D, which are assumed to be software-based, the Idea Sketch phase of the graphical user interface (GUI) is performed. If C and D are integrated into one software solution, a menu tree is developed to organize the required menu components for each screen. Subsequently, the GUI design is iteratively refined and evaluated. As this device combines multiple functions, numerous formative evaluations are conducted, focusing on the intended users. For GUIs, heuristic evaluations—an internal evaluation method—are performed multiple times; for user interfaces, cognitive walkthroughs, standard reviews, and similar methods are applied, ensuring ongoing refinement and incorporation of feedback into the design. Through these iterative evaluations conducted from the early development stages, a medical device with high usability can be achieved.

After completing the formative evaluation for each component, a comprehensive formative evaluation of the combined medical device must be conducted to assess any new hazards that may arise when functions are fused. This evaluation should identify potential problems or inconveniences associated with the integration of multiple functions, which may not be present in single-function medical devices. The insights gained from this analysis should then be reflected in the design to ensure optimal usability and functionality.

4) Medical Device with Validation

The final step is 'Medical Device Validation'. Initially, it is essential to confirm the extent to which user requirements are met. A summative evaluation should be conducted based on scenarios developed through risk analysis to ensure the safety and quality of the converged medical device. At this stage, after performing formative evaluations, the final prototype is assessed to ensure no additional risk occurs. This summative evaluation must consider the intended users and use environments analyzed during the 'User Needs' stage.

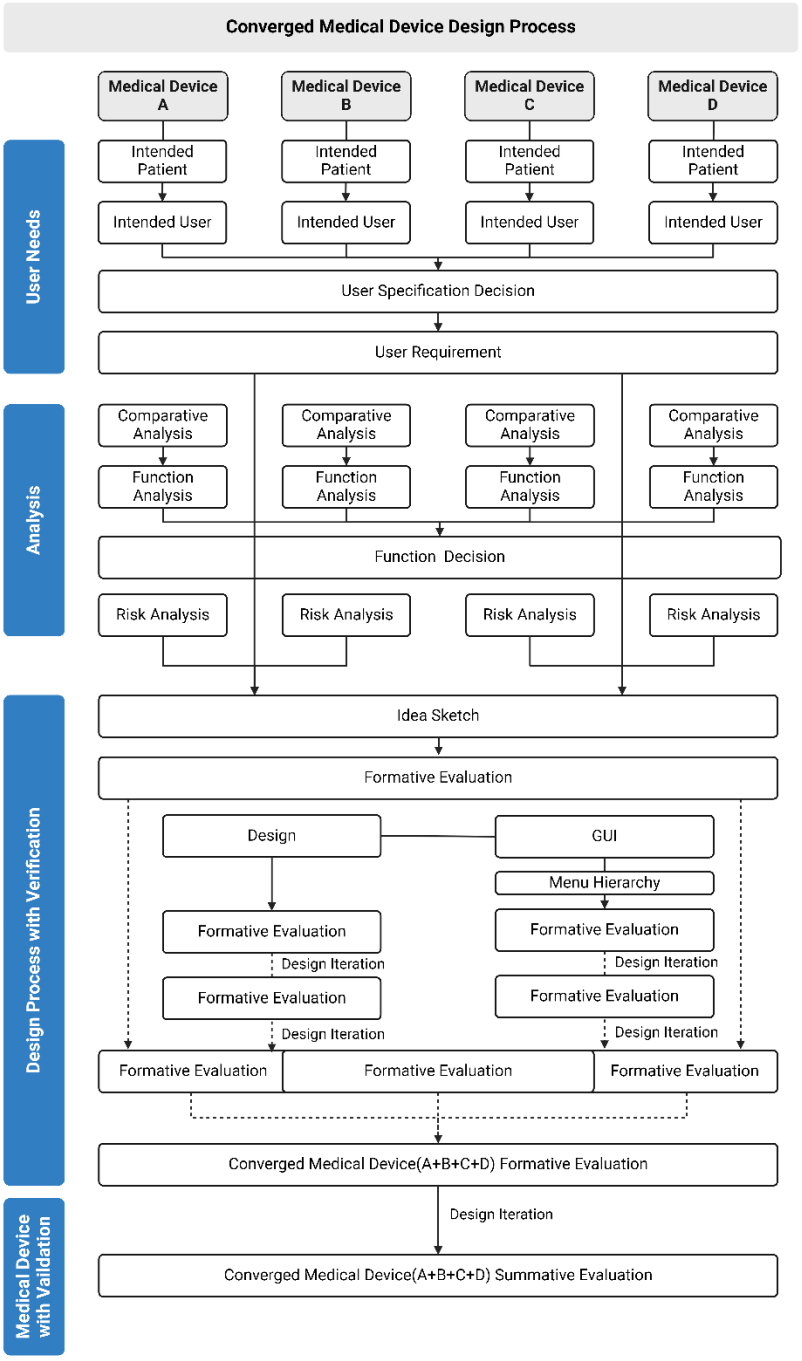


Figure 46. Converged Medical Device Design Process

4. DISCUSSION

This study proposes a 'Converged Medical Device Design Process' that incorporates the usability engineering process into the medical device life cycle design process to develop a highly usable design for a multifunctional convergence medical device, as opposed to a single-function medical device. When developing medical devices, various factors such as usability, risk management, individual specifications, and common standards must be considered. As converged medical devices are developed, these aspects become increasingly intricately linked. This complexity results from integrating several functions, therefore it is critical to fully comprehend each component's specifications, assess each function's usability, and then advance with the design by considering these insights.

Based on the 'Converged Medical Device Design Process' proposed in this study, the design process was applied to develop an incubator that integrates a warmer, phototherapy, and patient monitoring system. This is an example of a converged medical device, developed with careful consideration of actual user requirements in the 'User Needs' stage. In the actual clinical environment, when using a similar device, the infant must be lifted each time to measure their weight, the side door of the incubator must be opened to take an X-ray, and vital signs need to be monitored separately on the patient monitoring device. These issues have raised usability concerns.

Essential design parameters, including HR, SpO_2, Resp, NIBP, TEMP, Humidity, and Weight, were determined by functional analysis, risk analysis, and comparable device investigation in order to satisfy these requirements during the 'Analysis' stage. The graphical user interface on the control panel, which enables monitoring of bio signals from the converged neonatal incubator as well as temperature and weight within the incubator, is a unique medical device that converged an incubator,

warmer, patient monitoring system, and phototherapy. During the 'Analysis' stage, a comparative analysis showed that no such integrated device existed, nor was there a convergence of an incubator and patient monitoring system. Additionally, literature reviews, interviews with NICU medical staff, and direct visits to the NICU confirmed that there was no medical device available that combined all four functions. The graphical user interface from patient monitoring devices, which provides a straightforward display of biometric information, was integrated with the interface that manages parameters and settings within the incubator, and this combined functionality was incorporated into the design.

By analyzing existing similar devices, it was found that certain user requirements cannot be incorporated into the design due to patent restrictions on features like a rotatable mattress in other companies' products. Furthermore, through risk analysis, we were able to anticipate user behavior and mitigate risks through design. It was also confirmed that use errors related to alarms were the most frequently occurring issue. The location of the alarm indicator light and the positioning, dimensions, and form of the alarm message list were assessed during the 'Design Process with Verification' stage in order to resolve this problem and improve the correlation with risk analysis. Risk control elements were validated by examining hazards and hazardous situations identified through investigation and incorporating them into the scenario for the summative evaluation.

In the 'Design Process with Verification' stage, a total of 15 formative evaluations were conducted using usability evaluation methods such as surveys, focus group interviews, advisory panel reviews, expert reviews, and task analysis. Based on the characteristics of the converged medical device, the external system and software were evaluated separately. For the software’s graphical user interface, eight formative evaluations were conducted, and the design was revised seven times. The design considered factors such as menu button placement, alarm message display method, color, and size in accordance with ANSI/AAMI HE 75:2009 (R2018), and it was

continuously improved by incorporating user requirements and feedback.

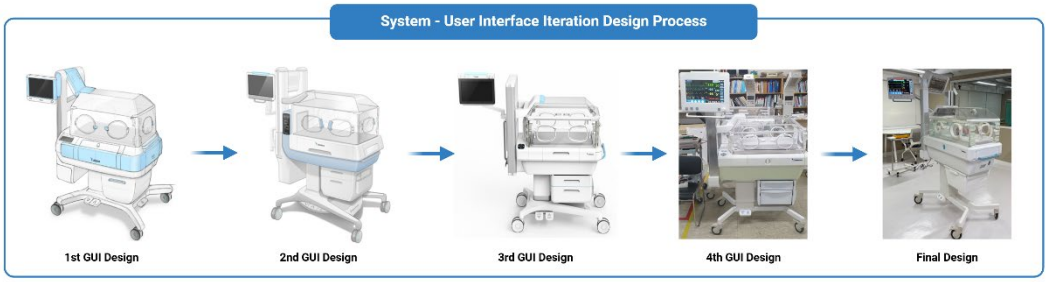


Figure 47. System Iteration Design Process

For the system, the overall external design was determined in the first and second formative evaluations, selecting features such as the flatness of the shell, the oval shape of the hand port, the design of the lock, and the physical bed tilting button. In the third formative evaluation, the shape of the physical buttons and scenarios for each button were established. The bed tilt functionality was extended to allow movement in all directions—up, down, left, and right—unlike existing incubators from companies like GE Healthcare, Dräger, and ATOM, which only allow up and down movement. To facilitate full mattress movement, the central buttons were redesigned to include upper and lower controls.

In the fourth and fifth formative evaluations, the overall external design was refined, with specific shapes selected for the monitor, caster lock, and drawer. The monitor's physical buttons were placed at the bottom for nurses' convenience. In the sixth formative evaluation, the sensor unit's position was optimized using a 3D rendering, and in the seventh, the physical display buttons were evaluated. While typical patient monitors lack buttons for phototherapy or incubator lighting, this converged design included additional buttons for phototherapy and incubator lighting to suit the neonatal incubator's requirements, along with the knob and alarm pause functions found in standard patient monitors.

The screen was enhanced in the third formative evaluation to display waveforms and numeric data simultaneously, allowing for concurrent monitoring of waveforms and values. In the fourth formative evaluation, visibility issues with the main screen were addressed by adding an on/off button for the warmer and phototherapy stages. Evaluations of the main screen's menu buttons were conducted in the fourth and fifth formative evaluations, reorganizing the most frequently used buttons at the bottom. The configuration was updated from 'Timer & Cals - Special Procedure - Patient Info - System Setup - Alarm Setup - Review Trend - Weight Measure - NIBP Measure' to remove the unused 'Timer & Cals' function and replace it with 'AI CARE - Patient Info - Special Procedure - System Setup - Alarm Setup - Review Trend - Weight Measure - NIBP Measure.'

In the sixth formative evaluation, the term 'Family Mode' was introduced as the new name for 'Kangaroo Mode,' a skin-to-skin treatment that provides warmth and bonding for premature infants in the incubator with their parents. In the seventh formative evaluation, alarm visibility was enhanced by changing alarm priority indicators from symbols to color and size modifications. Finally, in the eighth formative evaluation, the overall design was reviewed, and the menu buttons were updated to 'Patient Info - Special Procedure - System Setup - Alarm Setup - Review Trend - Weight Measure - NIBP Measure - AI CARE'.

Figure 48 represents the process by which the design of the graphical user interface (GUI) of the monitor attached to the incubator is modified.

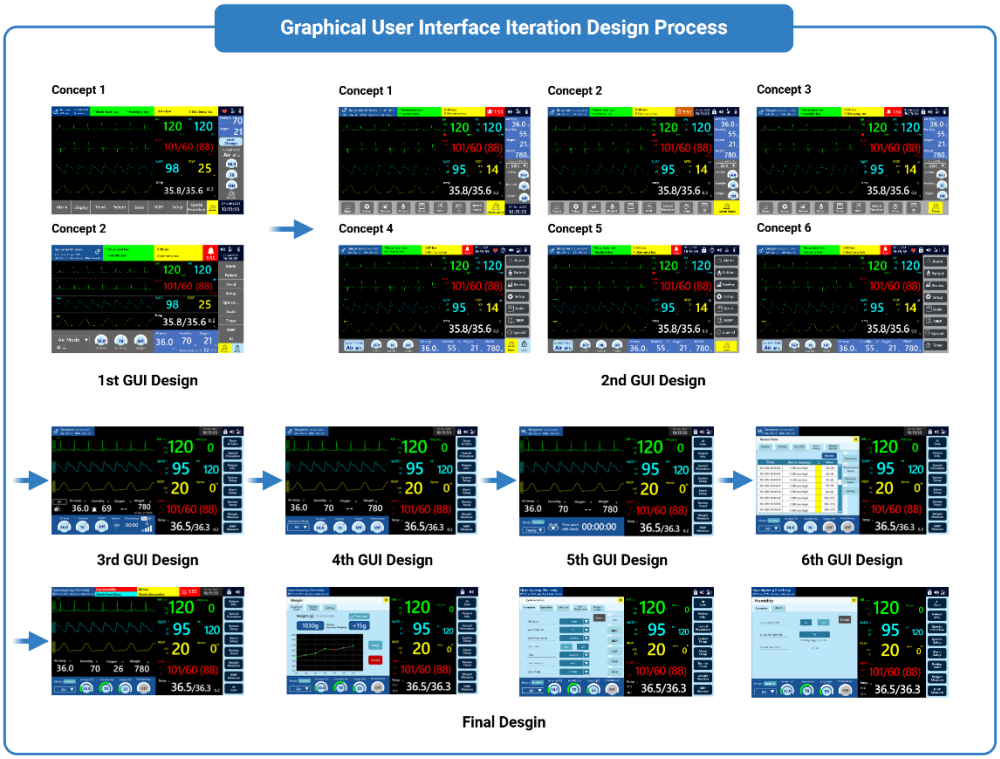


Figure 48. GUI Iteration Design Process

The 15 user requirements identified in the ‘User Needs’ stage were fulfilled in the final design. To alleviate the inconvenience of holding the patient and performing zeroing each time the patient’s weight is measured, an initial zeroing is done before placing the patient on the mattress, with automatic zeroing adjustments applied for subsequent measurements. The design, as shown in Figure 49, reflects this functionality. In the Weight menu, a red zeroing button is displayed. Once the zeroing is complete, the button changes to light green. After this, the weight can be measured using the weigh button located above the zeroing button or the weight measure button on the right side of the main screen.

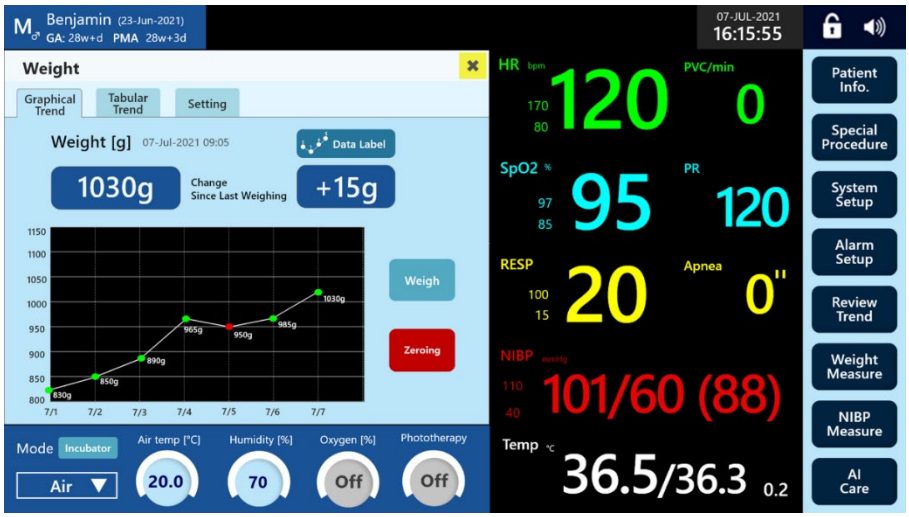


Figure 49. Weight Measurement Interface: User Needs(Calibration Without Lifting Baby)

The mattress was designed to meet requirements, allowing for not only up and down movements but also left and right movements. The screen was configured to move horizontally with an added stimulation function. The "Flipping, Sliding View for Vital Signs" user demand best captures the special features of the converged newborn incubator created in this study. The final design integrates temperature and humidity controls, which are typically monitored in a standard incubator, with patient parameters such as ECG, SpO2, RESP, NIBP, and TEMP, typically displayed on a patient monitoring device. These settings can now be viewed and adjusted on a single screen, allowing all parameters to be monitored seamlessly on a unified interface. This integration enhances usability by enabling the user to assess the patient's condition comprehensively on a single monitor, streamlining workflow and reducing the need to switch between devices. Figure 50 displays the screen that uses this feature.

Figure 50. Parameter Setting GUI for Incubator and Patient Monitoring Systems

The summative evaluation was a usability test conducted on both the system and software, following the steps of 'Medical Device with Validation.' The test results indicated a high success rate of 95.90%. Specifically, given the characteristics of converged medical devices, the incubator, patient monitoring system, warmer, and phototherapy each demonstrated success rates exceeding 95%. This high success rate is attributed to systematically incorporating user requirements from the

initial design stage and continuously refining the design through repeated formative evaluations. The high usability success rate of 95.90% achieved during the summative evaluation underscores the efficacy of iterative usability engineering. By incorporating user requirements and feedback from the early stages, this process mitigated critical usability risks and refined the design of the converged neonatal incubator. Features such as horizontal mattress movement, an integrated graphical user interface (GUI) for monitoring vital signs and adjusting environmental parameters, and the introduction of "Family Mode" for kangaroo care exemplify the importance of aligning design with real-world clinical needs. Furthermore, the integration of multiple functions into a single device addresses workflow inefficiencies commonly experienced in NICUs. For instance, the ability to monitor patient parameters, adjust incubator settings, and perform weight measurements on a unified interface reduces the cognitive and physical burden on medical staff, ultimately improving patient care and staff efficiency.

During the development of an incubator integrating four distinct medical device functions, a converged medical device design process was established by systematically deriving step-by-step analysis methods throughout the development stages, from initial prototyping to prototype completion. This design process was built on a thorough examination of key medical device design standards, including ISO 13485 and IEC 62304, with a particular focus on aligning the design process with regulatory requirements and best practices. The usability standard IEC 62366-1 was incorporated into the existing five-step medical device design process and the eight-step software medical device design process to identify relationships between the steps and ensure their seamless integration. By synthesizing the core elements of the medical device design process with usability engineering principles, four new design stages were developed to systematically link and enhance the usability and functionality of converged medical devices.

This integration ensures that usability considerations are embedded throughout the design cycle, allowing for the development of devices that meet both regulatory standards and user requirements while improving the overall safety and effectiveness of the final product.

Through the design process of the converged neonatal incubator, a converged medical device design process was established, proposing an overall design framework not only for the incubator but also for other converged medical devices, with a strong emphasis on incorporating usability considerations into the design. The proposed design process represents a paradigm shift in medical device development, emphasizing convergence and usability engineering as essential pillars of innovation. By addressing real-world clinical challenges through a user-centered approach, the process aligns with international trends in usability and risk management, paving the way for industry-wide advancements in healthcare technology.

In conclusion, the "Converged Medical Device Design Process" offers a transformative framework for designing multifunctional medical devices that prioritize safety, usability, and clinical efficiency. This study not only demonstrates the feasibility and benefits of convergence in medical devices but also sets a foundation for future innovations aimed at improving healthcare quality and patient outcomes. By embracing iterative risk analysis and usability engineering, the process ensures that medical devices are not only functional but also intuitive, safe, and effective for both users and patients.

5. CONCLUSION

The proposed "Converged Medical Device Design Process" is divided into the stages of User Needs, Analysis, Design Process with Verification, and Medical Device with Validation. NICU medical staff and usability experts, as the intended users of the converged incubator for each process, gathered to review and verify the usability of the converged medical device. In line with the specific characteristics of converged medical devices, regulatory and design requirements necessary for each component were investigated, analyzed, and integrated into the design.

As the importance of usability has recently gained prominence internationally, the demand for risk analysis of similar devices is also rising. Consequently, in alignment with the characteristics of the converged medical device under development, around 500 hazards and hazardous situations were gathered for each device, including incubators, warmer, and phototherapy units. Additionally, a total of 4,325 hazardous factors and situations were collected related to patient monitoring systems. In this study, several significant conclusions were derived from a risk analysis focused on usability. In incubators, for example, infants may become trapped if the canopy was locked, and there was a chance of falls when the side door was opened. While hazardous situations were noted for warmer or phototherapy units, such as the temperature staying high without an alert sounding, which may potentially cause patient burns, the risk of patient damage was associated with alarm problems for patient monitoring equipment.

The usability of the converged medical devices was finally demonstrated through summative evaluation after usability appropriateness was confirmed and integrated into the design through these numerous formative evaluation. This study showed that the 'Converged Medical Device Design Process' is promising not only for improving the usability and safety of multifunctional devices, but

for demonstrating the potential of a holistic, user-centered approach for future converged medical advancements. By systematically incorporating usability engineering from the early stages, this design process ensures that critical issues are addressed proactively, reducing the likelihood of post-market corrections or device failures due to design limitations.

Moreover, the results of this study highlight the importance of iterative risk analysis and usability verification in medical device design, especially for complex devices intended for high-stakes environments like NICU. By identifying and mitigating risks early, the process strengthens patient safety and improves workflow efficiency, supporting NICU staff in delivering effective, timely care. Looking ahead, applying this process across various types of medical devices, particularly those with convergence functions, could lead to industry-wide improvements in both device efficacy and user satisfaction. As a pioneering approach, this study provides a foundational framework for the 'Converged Medical Device Design Process,' addressing a previously unexplored area in usability engineering for converged medical devices. Currently, there is limited research on the longitudinal impact of such design process applied to converged devices. Future studies can build on these initial findings by conducting longitudinal evaluations to assess the long-term effects on patient outcomes and clinical efficiency. Additionally, as regulatory requirements evolve, adapting this process to meet new standards will be essential to ensure ongoing alignment with international trends in usability and safety. This study opens possibilities for further refinement and validation of the process, encouraging more extensive research to support its adoption in diverse healthcare settings.

In conclusion, the "Converged Medical Device Design Process" offers a viable framework that aligns with international trends in usability and risk management, underscoring the essential role of usability engineering in developing safe, effective, and user-friendly medical devices. This study demonstrates that convergence in medical devices, when paired with a rigorous usability approach, can significantly contribute to advancing healthcare quality and innovation.

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ABSTRACT IN KOREAN

융합형 의료기기 디자인 프로세스 내 사용적합성 엔니지어링 적용

융합형 의료기기는 여러 기능을 지닌 의료기기가 하나의 의료기기로 통합하여 사용자 편의성을 향상시키고, 공간 효율성을 최적화하며, 치료 결과를 개선하는 동시에 환자와 의료진의 부담을 경감하는 데 중요한 역할을 한다. 본 연구는 신생아 치료를 위한 보육기, 유아 가온장치, 환자 감시장치, 신생아 황달 치료용 광선 조사기를 하나의 의료기기로 융합한 융합형 신생아 인큐베이터의 설계 및 개발을 나타낸다. 이를 위해, 디자인 프로세스 내 사용적합성 엔지니어링 프로세스를 체계적으로 적용하여 사용자 중심의 안전한 디자인을 보장하고, 개발 과정에서 발생할 수 있는 잠재적인 문제를 최소화하기 위해 반복적인 사용적합성 평가를 진행하였다.

본 연구에서는 시스템 측면으로 총 7번의 형성 평가와, 그래픽 사용자 인터페이스(GUI) 개선을 위한 8번의 형성 평가를 수행하였다. 시스템의 유용성과 효율성을 평가하기 위해 수행한 총괄 평가에서는 전체 태스크 성공률이 95.90%를 나타나며 특히 환자 감시장치와 신생아 황달 치료용 조사기에서 각각 100%의 태스크 성공률을 달성하였다. 유아 가온장치와 관련 태스크에서도 97.78%의 성공률을 보이며 융합형 의료기기의 실용성 및 사용성을 입증하였다.

또한, 본 연구에서는 융합형 신생아 인큐베이터의 설계를 통해 융합형 의료기기 디자인 프로세스를 제시하고, ISO 13485(의료 기기 품질 관리), IEC 62304(소프트웨어 의료 기기 개발), IEC 62366(사용성 엔지니어링) 등의 국제 표준을 기반으로 디자인의 반복적인 개발 방식을 제안하였다. 이러한 접근은 융합형 의료기기의 사용성, 안전성, 효율성을 크게 향상시키는 데 기여할 수 있으며, 차세대 의료 기술 개발을 위해 확장 가능하고 실용적인 프레임워크를 제공하여 진화하는 임상 요구와 환자 중심의 치료 환경을 만족시킬 수 있음을 기대한다.

핵심되는 말: 융합형 의료기기, 디자인 프로세스, 사용적합성, 의료기기, 환자 감시장치, 보육기, 유아 가온장치, 신생아 황달 치료용 광선 조사기