THE HONG KONG POLYTECHNIC UNIVERSITY

INSTITUTE OF TEXTILES AND CLOTHING

DEVELOPMENT OF AN EYE-PATCH PROTECTOR FOR NEONATES

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A thesis submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

May 2008

CERTIFICATE OF ORIGINALITY

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ABSTRACT

Eye-patch protectors (EPs) are routinely used in neonatal units to protect neonates' eyes from strong light during phototherapy, which is a mainstream treatment for neonatal jaundice. However, problems of current EPs, such as suspicious photo-protection, easy displacement, eye irritation, and limited size, arise from practical use of the EPs in the public hospitals of Hong Kong. The objective of this research is to develop a comfortable, safe, secure and reliable EP that can provide maximum protection for neonates from potential retinal and corneal damage.

Based on the identified problems of the EPs currently used in the hospitals of Hong Kong, a set of design criteria for a new EP including photo-protection, comfort, easy handling, safety, disposability and appearance was established and related specifications were developed. 14 linear craniofacial dimensions were measured by applying a new, safe and convenient close-range photogrammetric measuring system and 2 circular dimensions were measured with a tape for pattern construction, development of a sizing system and a neonatal head model. A three-layer composite was designed for eye-patch panel with a cotton/Modal® blended knitted inner layer, a cotton woven middle layer and a cotton knitted outer layer. A bandage-type elastic material and a hook-and-loop fastener were selected for fastening panel. In conjunction with the design criteria and specifications, the anthropometric analysis, and the results of fabrication and the evaluation of fabric materials, an EP prototype

was designed and developed for optimizing its functional and practical performances.

The end-uses of fitting, comfort, security, safety, handling performance, and appearance of the new EP were evaluated by means of wear trial in the hospital. As a result, all respondents agreed that the new EP is better than two of current EPs except one who is taking care of a neonate suffering from dysphoria. The photo-protections of the new and the current EPs were further measured in a simulated clinical environment objectively. It showed that only the new EP and the Biliband® EP offered safe eye protection in its safety region whereas the new EP can provide significantly more security than the current EPs.

A product development model was formulated based on theoretical investigation and practical exploration of design and development of a new EP. The model is likely to provide a systematic and theoretic framework for the design and development of other protective textile products for neonates.

PUBLICATIONS ARISING FROM THE THESIS

Refereed Journal Papers

1 Y.M. Deng, K.L. Yick, Y.L. Kwok, S.C. Wong, S.P. Ng, "Development of a Three-Dimensional Measuring System for Infants' Head and Facial Morphology", *Journal of Donghua University*, 2007; 24(3).

2. Y.M. Deng, K.L. Yick, Y.L. Kwok, S.C. Wong, "Craniofacial Anthropometry of Neonates in Hong Kong for Development of an Eye-patch Protector", *Fibers and Polymers*, submitted.

3. Y.M. Deng, K.L. Yick, Y.L. Kwok, S.C. Wong, "Fabrication of Eye-patch Protectors Used in Phototherapy Treatment", *The Textile Institute*, in submission.

4. Y.M. Deng, K.L. Yick, Y.L. Kwok, S.C. Wong, "Light Protection Performance of Phototherapy Eye-patch Protectors for Jaundiced Infants", *Textile Research Journal*, in submission.

5. Y.M. Deng, K.L. Yick, Y.L. Kwok, S.C. Wong, Evaluation of the Photo-protection of Eye-patch Protectors Used in Phototherapy, *Journal of Donghua University*, submitted.

Conference Papers

1. Y.M. Deng, K.L. Yick, Y.L. Kwok, S.C. Wong, " Development of a Three-dimensional Photography-based Anthropometric System for Protective

Product”, *China International Wool and Wool Textile Conference & IWTO Wool Forum*, Xi’an, 2006.

2. Y.M. Deng, K.L. Yick, Y.L. Kwok, S.C. Wong, “Eye-patch Protector Design for Neonates in Hong Kong Used in Phototherapy Treatment”, *85th Textile Institute World Conference*, Colombo, 2007.

3. Y.M. Deng, K.L. Yick, Y.L. Kwok, S.C. Wong, “Development of an Eye-patch Protector for Neonates Used in Phototherapy Treatment”, *The Fiber Society Annual Meeting & Technical Conference*, Davis, 2007.

4. K.L. Yick, Y.M. Deng, Y.L. Kwok, S.C. Wong, “Development of an Eye-patch Protector for Infants”, *86th Textile Institute World Conference*, HongKong, 2008

ACKNOWLEDGEMENTS

First and foremost I would like to express my sincere gratitude to my chief supervisor Dr. Kit-lun Yick for her patient guidance and great support throughout the research. Her great encouragement helped me complete my study.

I would also like to express my gratitude to my co-supervisor Dr. Yi-lin Kwok, who shared her experience of developing hospital textile products. Her devotion to scientific research allows me to conduct my work logically and systematically, which will benefit me for the rest of my life. I owe my gratitude to my co-supervisor Dr. Siu-chun Wong for her help, support and guidance in the medical study. Her great encouragement and warmth will always be remembered.

I would like to express my gratitude to Dr. Bruce King. His kind help and patient guidance opened the door to my research and his friendship made me enjoy the hardships. Ms. Mow-nin Sun, Ms. Agnes Yeung, Dr. Ka-fai Choi, and Mr. Lv Zhao offered their support whenever I ran into problems of fabric testing, prototype design and manufacturing, and data statistic analysis. I would also like to thank all the people for supporting my study, including the medical staff in the Special Care Baby Unit of Queen Mary Hospital, my colleagues, and my friends.

Above all, I would like to thank my husband and daughter for their love and support in the past three years when I worked on my PhD study.

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CHAPTER 1: INTRODUCTION

1.1 Introduction

Neonatal jaundice is the most common condition found in neonates. About 50% of full-term neonates and 80% of pre-term neonates are affected in the first week of their life [1-3]. It is caused by bilirubin building up in the neonatal bloodstream. Bilirubin is a yellow toxin entity changed from hemoglobin, which is released by breaking down red blood cells. It is normally removed by the liver and is discharged from the body in the stool. If the neonatal liver is too immature to fully function, or if there is any other sort of abnormality, bilirubin will build up in the neonatal bloodstream. Kernicterus and bilirubin encephalopathy occur when the level of unconjugated bilirubin is excessive. Unconjugated bilirubin passing through the blood-brain barrier can cause permanent brain damage with chronic disability [4-6].

Phototherapy has been the most common therapeutic intervention used for the treatment of neonatal jaundice since it was first used in Rochford General Hospital in 1956 [5, 7-12]. Typically, a naked neonate is exposed to a fluorescent light for periods often exceeding 24 hours. The blue light is absorbed by the neonate's skin so that the bilirubin in the neonate's body is changed into another form of bilirubin that can be easily excreted in stools or urine. However, a study of animals reveals that intense blue fluorescent light can damage a newborn piglet's retinas which are developed in a way similar to those of human neonates [13-16]. Therefore, eye shields such as EPs,

thick layers of gauze, hood, opaque screen, and head-box are used in neonatal units routinely to protect the neonates' eyes from strong light during phototherapy [17-20].

1.2 Background of Research

Among various kinds of eye shields mentioned above, home-made and commercial EPs are commonly used in the local neonatal units in Hong Kong because they are small in size, easy to use and relatively cost-effective for clinical practice.

However, the level of eye protection given by current EPs is somewhat doubtful，particularly when phototherapy lights are shone from different positions. Traditionally, the light transmission of EP were only examined by measuring the light transmittance of material of EP [21, 22]. In clinical practice, because the required dosages vary according to the level and rate of the rise in serum bilirubin, the gestational/postnatal age of neonates, the hydration status, and the underlying cause of hyperbilirubinaemia, the level of light transmission characteristics given by the light units vary with each power source and light condition, such as wavelength, intensity, light distance, and angle [23]. When considering the potential hazards of phototherapy light to the cornea and/or retina, an EP that gives effective and comprehensive protection from different sources and positions of light must be developed.

There are also some drawbacks to the current EPs. An ill-fitted EP can result in light gaps and the exposure of the neonate's eyes to the external environment and/or the bright light during phototherapy. Moreover, during the phototherapy treatment, the

head movement of the neonate can cause EP displacement quickly and frequently, allowing the light to shine directly into the neonate's eyes. According to some local pediatricians, the moulding of the neonate's head during delivery also makes an EP difficult to be held in a secure position. Pediatricians must reposition the EP frequently to prevent accidental light exposure. In clinical practice, the current EPs purchased from American suppliers can only offer limited size that cannot provide optimum fitting for local neonates due to geographic and body-size differences.

Moreover, the gauze layer applied to the EP and replaced every day to avoid eye infection by local medical personnel may be too rough and can cause irritation and excessive rubbing on the eyelids, corneal abrasion, and even eye infection [24]. It may even reduce light protection for neonates due to light gaps and ill-fitted EPs. Binding the EP too hard with the aim of fixing the EP more securely can cause bruises around the neonate's eye.

Because of the above-mentioned drawbacks, there is a strong need for developing a new EP which can offer comprehensive eye protection to neonates under the strong light of phototherapy in the local neonatal units.

1.3 Objectives of Research

Based on the shortcomings of the current EPs, the objectives of this research are:

(1) To establish a thorough scientific basis for understanding the contact conditions of EPs, such as the light transmittance levels in relation to different light

conditions, the neonate's treatment/care, and characteristics of current EPs, in order to create design criteria and specifications.

(2) To measure and analyze the anthropometric characteristics of neonates in a neonatal unit in order to develop an optimum-fitted EP.

(3) To evaluate different types of textile materials in terms of physical comfort properties, functional properties, and various fastening systems in order to select an appropriate textile material and a fixation method of developing an EP with optimum comfort and functional performance for use in a neonatal unit.

(4) To design and develop, on the basis of clinical and scientific analysis, an EP which shields the neonate's eyes effectively and securely improves physiological comfort and reduces eye infection.

(5) To undertake laboratory tests and clinical trials to evaluate the effectiveness and the practical use of the EP.

(6) To formulate a product development model to provide a framework for developing protective textile products.

1.4 Research Scope and Methodologies

The research has four aspects: phototherapy conditions and medical practice, development of an EP prototype, evaluation of the EP, and development of a product model. The details are illustrated in Figure 1-1.

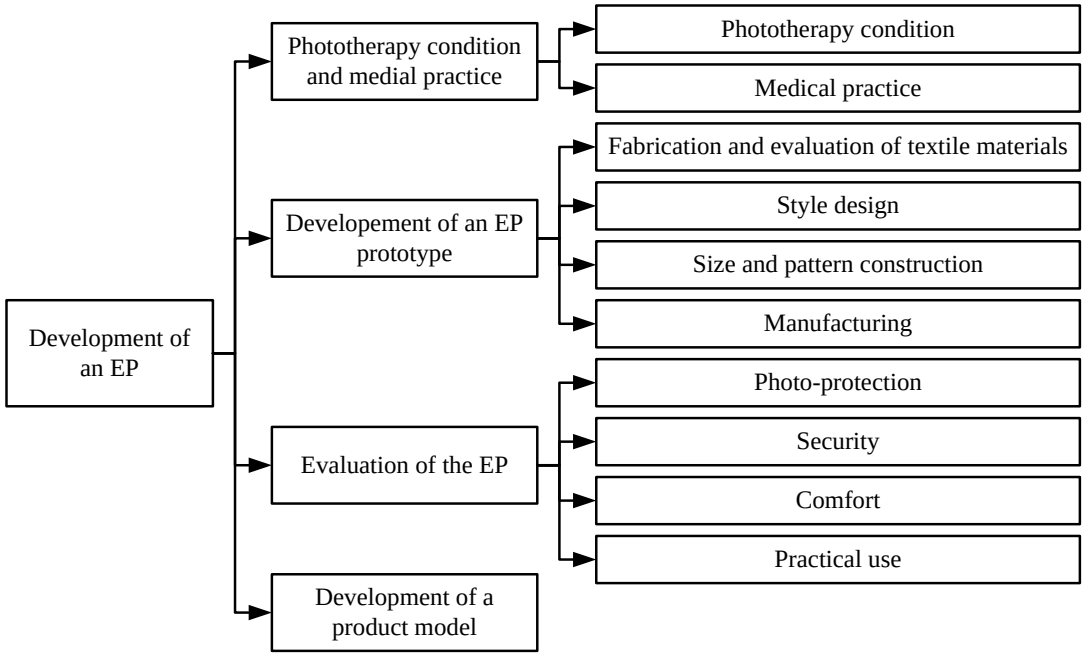


Figure 1-1: Scope of the research

The research methodologies include:

(1) Study contact conditions of EP

An extensive scientific basis for understanding the contact conditions of the current EPs is derived from extensive literature, clinical observation, focus group interviews, and questionnaire surveys. The levels of light transmission (i.e. irradiance and illuminance) inside an incubator/warm bed in terms of wavelengths, intensities, sources, light angles, and distances used for phototherapy treatment are evaluated.

(2) Anthropometric measurements of neonates' craniofacial morphology

Various anthropometric measuring methods in the literature are identified and compared. The critical requirements for the measurement of neonates in a clinical situation are analyzed and an appropriate measuring method is developed. Related

dimensions and neonatal basic information are collected in order to develop an optimum-fitted EP.

(3) Product design and development

On the basis of theoretical analysis and clinical investigation, prototypes of EPs are designed and developed. A series of textile materials and fastening systems (methods of fixing) is subjectively and objectively evaluated in terms of light transmission level, physical and physiological comfort properties, hospital safety, etc. In conjunction with the results derived from the anthropometric measurements of the neonates, the specifications of the EP are formulated for developing the best-fitted protector in terms of size, cost, safety standards, and for optimizing its practical and functional performance.

(4) Laboratory test and clinical trial

A laboratory test is carried out in an environment-simulating system, which can simulate a phototherapy environment in a neonatal unit. The light characteristics that the neonate's eyes receive are evaluated in terms of different light sources of wavelengths and intensities, and light angles and distance used for phototherapy treatment. A series of clinical observations and clinical wear trials is also carried out at Queen Mary Hospital (QMH) to evaluate the functional, comfort and practical properties of the new EP.

(5) Product development model of EP

A product development model is generalized based on modification of Orlando's protective clothing design process. The Analysis of Interconnected Decision Areas Technology (AIDA) is adopted especially to formulate a comprehensive, externalized and strategy–control design methodology for the process of conceptual design.

1.5 Research Significance and Value

In this research, scientific clinical experiments for measuring contact conditions of EP, such as the light transmittance levels in relation to different light conditions and anthropometry analysis, are conducted. Accompanied by extensive investigations into both textile science and design processes, an EP is developed. A product development model is finally formulated to provide a framework for designing and developing protective textile products for neonates.

The main deliverable of the research is the new design of a comfortable, safe, secure, and reliable EP for neonates nursed in a neonatal unit when they are exposed to bright light. This research is also valuable in providing a conceptual framework for design, development, and evaluation of protective textile product for neonates during a specific therapy.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

EP is a kind of protective textile product, which must meet all critical and extensive requirements for textile products in a hospital. The greatest challenge of developing a protective product is to meet all requirements which usually compete against each other in a single best design. To develop a new EP with optimum protection, comfort, and safety for neonates in phototherapy treatment, the following related study areas are scrutinized: (1) physiological mechanisms of EP and phototherapy treatment. The study of mechanisms of EP is concerned with the anatomy and physiology of neonate's eye which reveals how an EP works and how it performs photo-protection. The study of phototherapy treatment which concentrates on the measurement of light condition under phototherapy can be used to unveil the characteristics of phototherapy light and effectiveness of bilirubin degradation; (2) fabrication and evaluation of textile materials. These aspects are related to the influence of the textile quality for photo-protection and other properties of EP, such as comfort and safety; (3) anthropometry of neonates. This study shows the characteristics of current anthropometric measuring systems, from which an appropriate measuring system for neonate use in the neonatal unit might be developed. It also reveals the craniofacial characteristics of human being from which some measuring dimensions for developing an effective and secure EP might be derived;

(4) clothing product design and development. It provides a theoretical basis for EP design and development. The overview of the literature review is presented in Figure 2-1.

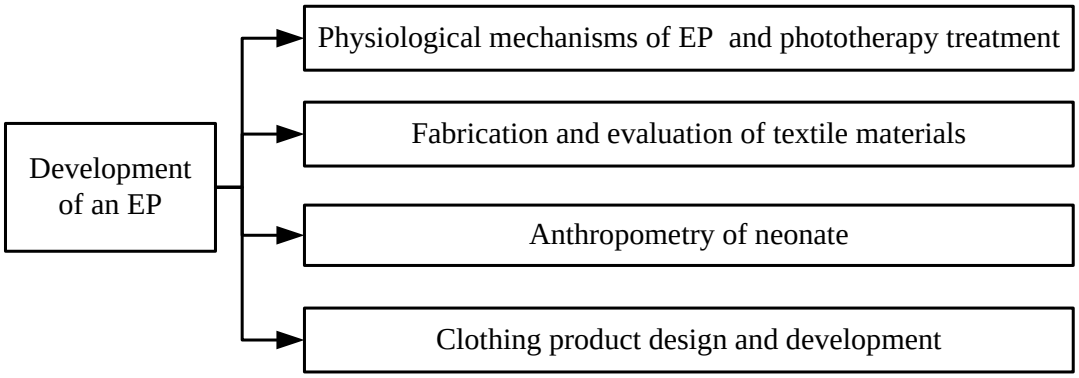


Figure 2-1: Overview of the literature review

2.2 Physiological Mechanisms of EP and Phototherapy Treatment

2.2.1 Anatomy and Physiology of Eyes and Skulls

Sound knowledge of anatomy and physiology of human eyes and skulls is essential to understand the significance of how EPs protect neonates from strong phototherapy light and how EP works.

2.2.1.1 Anatomy and Physiology of Eyes

Eyes are the most complex sensory organ of human beings. Vision obtained by eyes is so dominant that 70% of sensory receptors in the body are in the eyes, and

nearly half of the cerebral cortex plays a part in visual processing [25].

The structure of a human eye is shown in Figure 2-2. The outer layer is divided into two parts: anterior cornea and posterior sclera. The cornea is transparent and approximately spherical with a radius of curvature of about 8 mm. The sclera is a dense, white, opaque, fibrous tissue that is mainly protective functionally and is approximately spherical with a radius of curvature of about 12 mm. The middle layer of the eye is the uveal tract, which is composed of an iris anteriorly, a choroid posteriorly, and an intermediate ciliary body. The iris performs an important optical function through its aperture; the ciliary body is important to the process of accommodation, and both the ciliary body and the choroid support important vegetative processes. The inner layer of the eye is the retina, which is an extension of the central nervous system and is connected to the brain by optic nerves. The retina contains millions of photoreceptors that transduce light energy and other neurons involved in the processing of light stimuli and glia. The retina is commonly called the sensory tunic and its neural layer plays a direct role in vision. The inside of the eye is divided into three compartments: anterior chamber, posterior chamber and vitreous chamber [26].

Image-forming light enters the eye through the cornea, and is refracted by the cornea and the lens to be focused on the retina. In phototherapy treatment, the intense blue fluorescent light can damage the retinas of neonates while the abrasion of the cornea may be caused by the rough surface of the EP [21]. That means that the neonate’s vision can be affected or even completely lost, which harms its

physiological and psychological development badly.

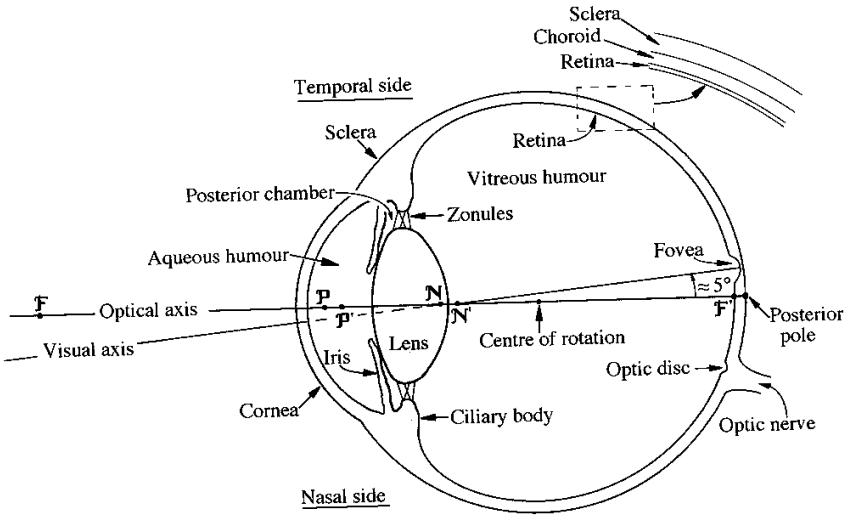


Figure 2-2: Internal structure of the eyes

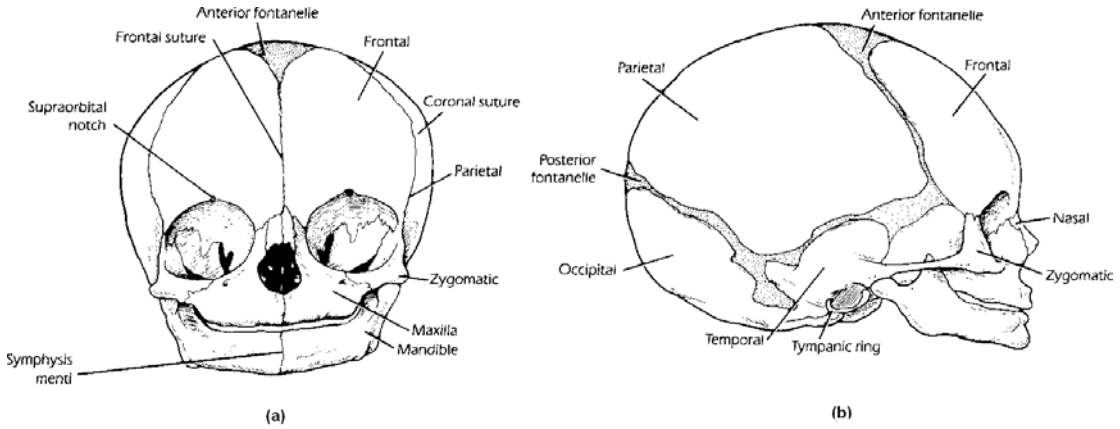
2.2.1.2 Anatomy of Skull

The skull consists of a number of separate bones united by immobile joints called sutures. The skull mainly consists of bones of the cranium and bones of the face. The cranium consists of 1 frontal bone, 2 temporal bones, 2 parietal bones, 1 sphenoid bone, 1 occipital bone, and 1 ethmoid bone. The facial bones consist of 2 zygomatic bones, 1 vomer, 2 maxillac, 2 palatine bones, 2 nasal bones, 2 inferior conchae, 2 lacrimal bones, and 1 mandible. The orbital margins are bounded by the frontal bone superiorly, the zygomatic bone laterally, the maxilla inferiorly, and the processes of the maxilla and the frontal bone medially.

Compared with the adult skull, the neonatal skull has a disproportionately large

cranium relative to the face [27]. More importantly, the shape of the neonatal skull is usually elongated during delivery and it changes in the first few weeks. The neonate's head circumference is the greatest measurement around the forehead and the occiput describing the head size, and normally measures between 330 and 370 mm, with the average of 350 mm. During the first month of life, the head circumference normally grows by about 20 mm [28].

As the EP is used for eye protection, the anatomy around the orbit is the foundation of designing an eye-patch panel while the fastening system design should take the skull's shape and structure into account.



(a) The anterior aspect (b) The lateral aspect

Figure 2-3: Neonatal skull

2.2.2 Phototherapy Treatment for Jaundice

In this section, the physical nature of light, and the principles and conditions of phototherapy light are reviewed.

2.2.2.1 Electromagnetic Spectrum of Light

Light is a form of radiant energy. It is sent out through the space by luminous source. The distribution of energy among the various constituent waves is called the spectrum of radiation, and the adjective spectral implies dependence on the wavelength. An electromagnetic spectrum is presented in Figure 2-4. The narrow spectrum of approximately 380 to 770 nm is capable of producing a visual sensation in human eyes and is referred to as “light” [29].

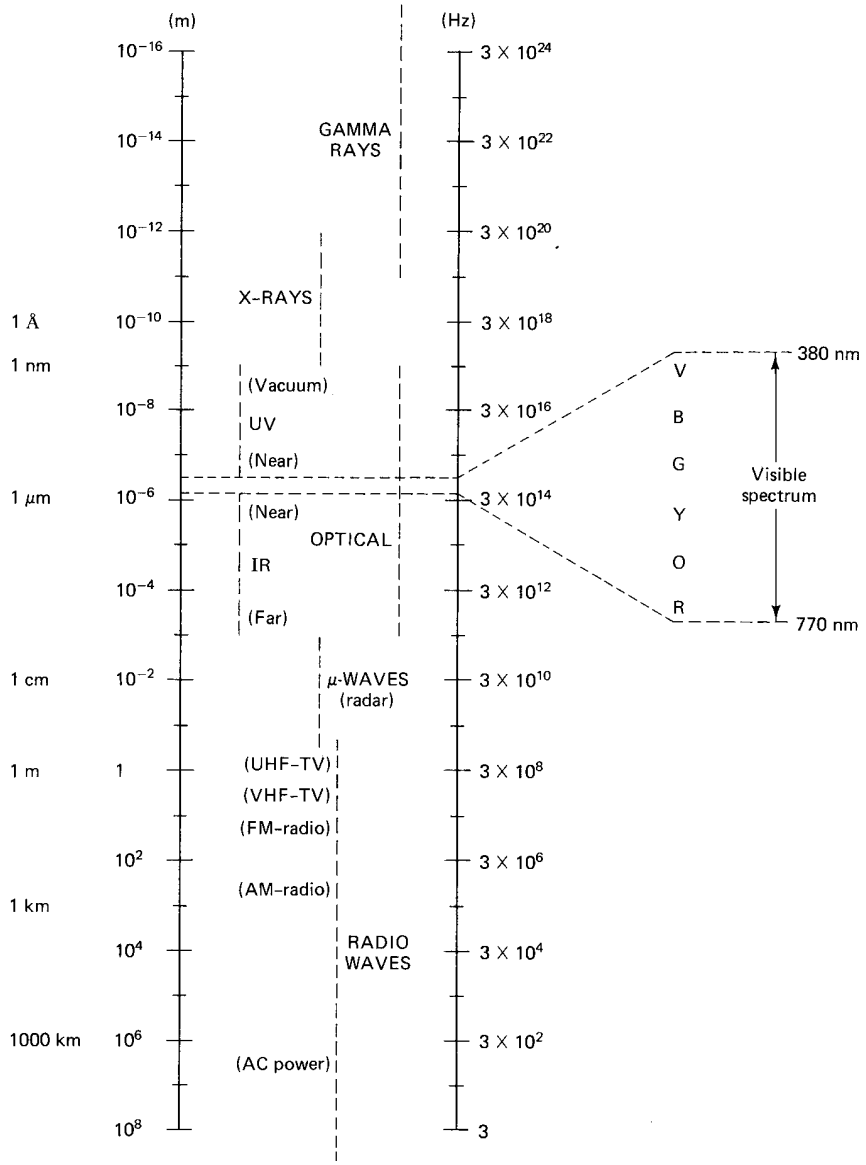


Figure 2-4: Electromagnetic spectrum with high-lighted visible spectrum

2.2.2.2 Mechanism of Light Transmission

Light from a source in an isotropic homogeneous medium continues to travel in the form of straight ray or expanding wavefront until it meets the surface of other media. On the surface, a number of effects can occur, depending on the nature of the two media and that of the surface in between. In all cases, one part of light is sent back or reflected. The remainder passes into a new medium, where one part of it is turned into some other forms of energy or absorbed by the new medium, and the other part continues to travel through the new medium for transmission [29, 30]. The descriptions of the three effects are:

(1) Reflection: There are two types of reflection. One is regular or specular. When the surface is polished, most reflected light travels back in definite directions, as though it came from a source placed in a new position. Another is irregular or diffused and the light is diffused or scattered. When a surface is not polished, every irregularity of the surface reflects light in a different direction and the light does not return as a definite beam.

(2) Absorption: When light enters a new medium, it is changed into some other forms of energy after traveling a short distance and is absorbed. The amount of absorption depends on the properties and thickness of the material.

(3) Transmission: It is a fraction of incident light on a specified wavelength that passes through a medium.

When direct light falls onto a textile, part of the radiation is reflected, the material absorbs another part, and the remainder passes through the textile (see Figure

2-5).

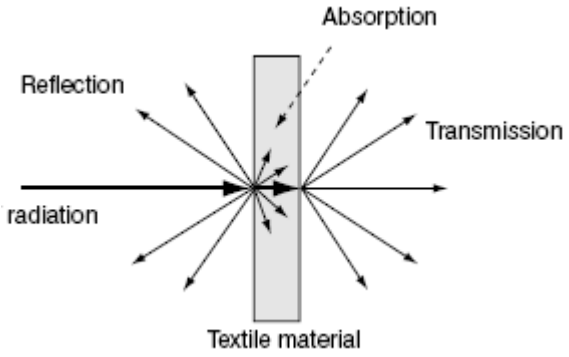


Figure 2-5: Reflection, absorption and transmission of light radiation

2.2.2.3 Radiometric Quantities for Radiation

In radiometry, the science of measurement of electromagnetic radiation, many radiometric terms, such as radiant energy, radiant flux, irradiance, radiance, luminous energy, illuminance, and luminance, have been introduced and used to characterize the energy content of radiation [29]. Among these terms, irradiance is used for measuring the energy output of phototherapy to ensure efficiency of treatment, and illuminance is used for quantifying the light dose affecting a human being's visual system [9, 15, 31, 32].

(1) Irradiance (*Ee*): Irradiance is a radiometry term for the power of electromagnetic radiation on a surface per unit area, and is used when electromagnetic radiation is incident on the surface. The SI unit for this quantity is watts per square metre (W/m^2). It is common to consider each frequency in the spectrum separately. When separation of spectrum is done for radiation incident on a surface, it is called

spectral irradiance and has SI units W/m^3, or commonly $W/m^2/nm$.

(2) Illuminance (*Ev*): Illuminance is a photometry term for flux density. It is the total luminous flux incident on a surface per unit area, and a measure of the intensity of incident light, wavelength-weighted by the luminosity function to correlate with human brightness perception. In SI-derived units, illuminance is both measured in lux (lx) or lumens per square metre ($cd \cdot sr/m^2$).

2.2.2.4 Characteristics of Phototherapy Light

The efficacy of phototherapy depends on the fundamental laws of photobiology and photochemistry. The interaction of phototherapy with bilirubin causes a photochemical change that is therapeutical, and this makes phototherapy of neonatal jaundice possible. The therapeutic efficacy of phototherapy is dependent primarily on the following factors: (1) the spectral qualities of the delivered light (wavelength range and peak), (2) the intensity of light (irradiance), (3) the exposed body surface area (BSA), (4) the skin thickness and pigmentation, (5) the total bilirubin at the clinical presentation, and (6) the duration of exposure. Among these factors, the spectral qualities of the delivered light (wavelength range and peak) and the intensity of light (irradiance) are largely related to the photo-protection level of EPs.

At present, the optimum light quality for the most efficient use of phototherapy is still under active investigation and discussion. The yellow bilirubin absorption spectrum in plasma and buffer/human serum albumin has been well established. The

most effective light sources for degrading bilirubin in the skin are those that emit light in a relatively narrow wavelength range of 400-500 nm and center around a peak of 460±10 nm, which closely matches the bilirubin absorption spectrum [8, 23]. It should be noted that recent research shows that the use of green or blue-green (turquoise) light with a peak emission of 490 nm is nearly as effective as blue light when decreasing the total bilirubin in vivo [33].

Irradiance refers to the number of photons directed to or received per square cm of the exposed BSA. Deliverable spectral irradiance is different for each type of light source and is dependent on its design and the distance between the light source and the patient. According to the current American Academy of Pediatrics (AAP) clinical practice guidelines, standard phototherapy units deliver 8-10 μw/cm^2/nm and intensive phototherapy units require more than 30 μw/cm^2/nm [34].

2.2.2.5 Characteristics of Phototherapy Unit

There are many types of commercial phototherapy units, including:

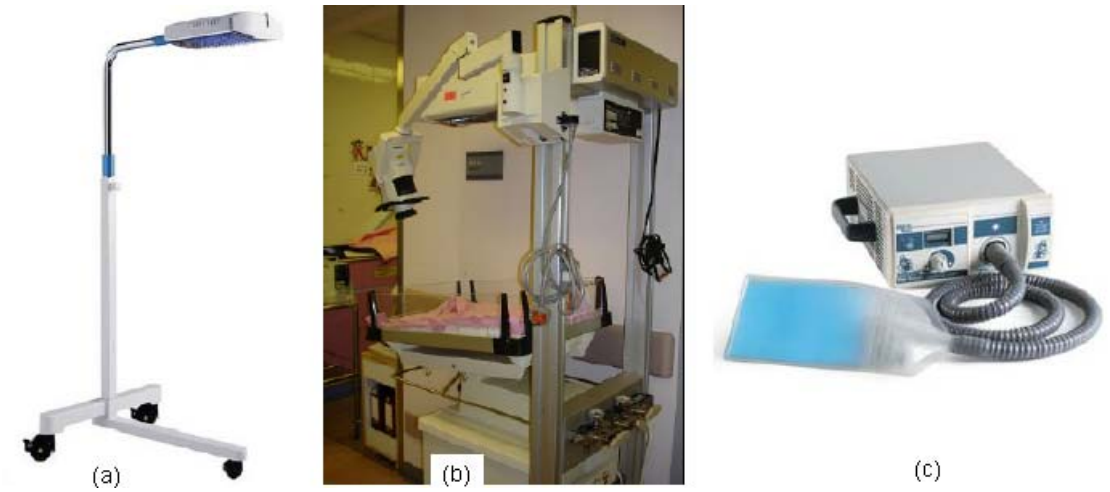
(1) Fluorescent Lights: Fluorescent light is the most popular phototherapy unit (see Figure 2-6 (a)). Different colors of light are used in fluorescent light sources, namely (a) cool white, (b) blue, (c) special blue, (d) turquoise, and (e) green. Cool white light has also been used together with special blue tubes to ameliorate carers' complaints regarding the blue hue of the light. At the distance of 400 mm, 2 white and 2 blue tubes can deliver up to 11 μW/cm^2/nm while 4 blue tubes can deliver up to 24

μW/cm^2/nm.

(2) Halogen Spotlights: Halogen spotlights utilize single or multiple metal halide lamps and can provide fairly high irradiance often over 20μW/cm^2/nm (see Figure 2-6 (b)). However, it can generate considerable heat and cause thermal injury to the neonate and unwary staff alike if applied too closely.

(3) Fiberoptic Systems: Fiberoptic phototherapy has been available since the late 1980s [35]. The metal halide bulb remains the source of light, but it can be placed in direct contact with the neonate because the pad or blanket emits insignificant levels of heat (see Figure 2-6 (c)). The fiberoptic inlet thermal protector allows the neonate to touch the pad directly and offers an irradiance of up to 45 μW/cm^2/nm. In phototherapy treatment, the neonate sleeps on the pad directly.

(4) LEDs: The light source of the new semiconductor devices is high-intensity gallium nitrate LEDs. It has many advantages, such as a more efficient conversion of electrical energy, a narrow spectrum of light (470±60 nm) overlapping the peak of the bilirubin absorption spectrum, the technical possibility of delivering narrow bilirubin, specific band spectral irradiances of up to 100 μW/cm^2/nm, a long lifetime, no side effects to the carer, and applications such as blankets, wraps, or even clothing.



(a) Fluorescent Light (b) Halogen Spotlight (c) Fiberoptic System

Figure 2-6: Phototherapy units

2.2.3 Previous Works of Phototherapy Light Measurements

In this section, previous studies about the characteristics of phototherapy light (i.e. wavelength, intensity, etc.), the unit and setting, and its effectiveness for bilirubin degradation are reviewed and summarized in Table 2-1. The results show that the wavelength and the irradiance of light are two essential parameters of phototherapy light affecting the required dosage for jaundice treatment [7]. Dicken and Levene *et al* revealed that the most efficacious wavelength range for photo-degradation of bilirubin is between 450 and 460 nm (i.e. blue light). To some extent, the wavelength at 420 nm and 490 nm may also contribute to bilirubin degradation [7, 10, 33]. Optimal therapeutic irradiance has yet to be adequately defined. Sisson and Tan found that the reduction in serum bilirubin is proportional to the amount of radiant flux within the 400-500 nm wavelength and suggested that irradiance should be a standard index to

denote the intensity of light [23]. Bonta *et al* examined the effective irradiance for phototherapy (at least 4.0 µw/ cm^2/nm corresponding to approximately 340 ft-c) [9, 11]. In view of the light intensity evaluation, light irradiance is generally used since it is highly related to the distance between the light unit and the diffuser of the instrument. Radiometers are used in several studies for measuring irradiance and spectroradiometers are more appropriate for mapping spectral irradiance plots [7, 11, 23, 36].

The light sources and settings affect the characteristics of light mainly. There are many studies about the distance between diffusers and units. The results show that the distance of 450 mm is typically applied to clinical practice, considering the relationship between the light unit, the incubator and the neonate [7, 33]. Levene demonstrated that the locations of the neonate on the mattress can significantly affect the light irradiance reaching the neonatal skin [10].

Table 2-1: A summary of previous studies of phototherapy light measurements

Year	Researcher (s)	Methods/ Instruments	Results
1976	Bonta *et al* [11]	1) Radiant flux was measured by a 1L 155 Color Radiometer in 400-500 nm while foot-candles were measured by a Tri-Lux foot-candle meter. 2) Conventional units were placed 420 mm from the light source to the neonate while intensive care units were at an average distance of 1000 mm from the source to the neonate.	1) At least 4.0 μw/ cm^2/nm, approximately 340 ft-c, was required for effective phototherapy.
1980	Levene [10]	1) The light intensity of phototherapy units was recorded in various positions. 2) The fluorescent unit is at the back of the incubator with a distance of 450 mm from an Air-Shields radiometer (unit: μw/cm^2).	1) A neonate nursed on the front third of the incubator mattress receives less than 40% of the maximal light incident on the centre of the mattress.
1980	Levene *et al* [37]	1) Two phototherapy units, Air-Shield S400 and Vickers Medical, were fitted consecutively with four white tubes, four blue tubes and a combination of two blue and two white tubes. 2) The light unit was placed 450 mm directly over the incubator. Glass microcapillary tubes of bilirubin was placed at the center of the mattress of the incubator	1) White light was less effective than pure blue light or the combined light of white and blue 2) The Vickers Medical unit was better than the Air-Shield S400 for degrading bilirubin. 3) To some extent, the 420 nm wavelength also contributed to bilirubin degradation.
1982	Tan [23]	1) The light measurements were made by an 11A photometer/radiometer.	1) Irradiance was important as the percentage of bilirubin declined when irradiance increased. 2) A more effective phototherapy could be expected if irradiance increased to 2 mW/cm^2 or higher.
1983	Modi *et al* [9]	1) Measurement of irradiance was made by a Macam R450 radiometer in 430-475 nm.	1) Phototherapy without measurement of irradiance was incomplete and inefficient.

Table 2-1: A summary of previous studies of phototherapy light measurements (continued)

Year	Researcher (s)	Methods/ Instruments	Results
1985	Landry *et al* [31]	1) Measurement of the intensity of the optical radiation (radiometric data) and that of the optical radiation weighted for visual response (photometric data) about ambient light and phototherapy conditions of 8 neonatal units were obtained.	1) The irradiance of ambient units in 400-675 nm is 342±153 μW/cm^2 and 68±33 ft-c. 2) The mean irradiance of the phototherapy unit on the 400-500 nm wavelength was 714 μW/cm^2 with 97 μW/cm^2 S.D.
2000	Dicken *et al* [7]	1) The phototherapy unit was measured by a Bentham double monochromator spectroadiometer system calibration traceable to NPL on the 350-600 nm wavelength. 2) Measurements were taken 350 mm below the lamps in the center of the field.	1) A technique was proposed for normalizing the output of different systems to make comparison easier and to enable optimal treatments to be designed. 2) Requirements for optimizing phototherapy: wavelength of 430-530 nm, the highest irradiance in excess of 2 mW/cm^2 and irradiating the largest area of the skin.
2003	Ebbesen *et al* [33]	1) Six of the turquoise fluorescent lamps plus two daylight lamps, and six of the blue fluorescent lamps plus two daylight lamps were evaluated. 2) The distance between the light unit and the surface of the neonate was 320 mm.	1) The turquoise lamps with an emission peak at 490 nm and a bandwidth of 65 nm were preferable because of the more efficient reduction in plasma bilirubin concentration in relation to light irradiance and the less severe side effects.
2005	Hart and Cameron [36]	1) An International Light IL1700 radiometer with a SED 033 detector, a “BR” bilirubin filter and a “W” cosine diffuser were used. 2) Measurements of overhead phototherapy systems were taken when the distance between the unit and the diffuser was 450 mm at the center of the field.	1) Three of the seven phototherapy systems did not reach irradiance of 2 mW/cm^2 and deliver lower total irradiance.

2.2.4 Use and Effectiveness of EPs

The application of EPs to phototherapy treatment has a history of over 40 years [38]. Various EPs have been developed and applied to phototherapy as they have more advantages than other appliances such as hoods [19, 39, 40]. Since the essential function of an EP is photo-protection, the protection given by an EP must be evaluated. Much research has focused on evaluating light transmittance through EPs (see Table 2-2). Porat and Robinson *et al* emphasized that the evaluation of EPs should be conducted in a clinical light simulating environment [22, 41]. Robinson *et al* used a spectroradiometer to measure the spectral distribution of irradiance which is an effective index for the dose of phototherapy in clinical practice while Davies and Porat e*t al* used a luxmeter (or lightmeter) to measure illuminance and evaluate the intensity of incident light, wavelength-weighted by the luminosity function to correlate with human brightness perception [22, 41, 42].

Importantly, Davies *et al* revealed that there is an increased risk in retinopathy of prematurity (ROP) for very low birth weight neonates exposed to ambient light levels higher than 600 lux and it is used as a reference to identify which EP can offer safe photo-protection [42].

In these research studies, home-made EPs of one or three layers of tubular stockinette folded with or without oval eye pads, EPs made of a thin (single or double-layered) woven fabric, colored felt, cotton wool, or a gauze (single or multi-layered), and commercial EPs including Bili-mask®, Posey®, tinted plastic shields, and orthoptic eyepatch, have been evaluated. Bili-mask® is one of the most

effective EPs.

Table 2-2: Previous works of EP evaluation

Year	Researcher (s)	Methods/ Instruments	Results
1986	Davies *et al* [42]	1) Seven eye masks were measured by a Sekonic luxmeter under four different phototherapy units	1) Several eye masks used in local NICUs did not reduce the light intensity during phototherapy to ≤ 600 lux.
1986	Porat *et al* [43]	1) Light penetrance through tubular stockinettes of various layers and stockinettes with eye pads and a bili-mask was assessed by a Minolta Autometer IIIF using a phototherapy unit at 18 inches from the light source Measurement was taken through a 35 mm-diameter opening in a dark cell.	1) Neonate's eyes were best shielded by the bili-mask.
1987	Chin *et al* [21]	1) The light transmission of 12 types of phototherapy eye-shields were measured by a Perkin-Elmer 330 spectrophotometer in the wavelength range of 250-800 nm	1) All eye-shields showed a peak light transmission of < 0.1% and commercial eye-shields offered an advantage of eye protection over the local-made ones. 2) The choice of shields may be less important than how they are secured over neonatal eyes.
1988	Moseley *et al* [44]	1) The transmission of tinted plastic shields was measured.	The measured shields were not suitable for protecting neonatal eyes in phototherapy.
1989	Ostrowski *et al* [19]	1) Blue light radiance (generated by a Phototherapie 800 fitted with a single 200W mercury-halogen lamp) was measured by a radiometer (R 450-RAD) when eye protection was provided by a phototherapy hood	1) Neonatal eyes should be protected by eye-patches when triple phototherapy lamps were at the foot-end of the incubator.

Table 2-2: Previous works of EP evaluation (continued)

Year	Researchers	Methods/ Instruments	Results
1989	Porat et al [41]	1) Five different eye shields were evaluated by a lightmeter (Minolta autometer IIIF) under a phototherapy unit (Healthdyne, Marietta). This unit has illumination of 200-2400 ftc and a wavelength of 400-500 nm was placed 460 mm from a dark cell that had a 30 mm-diameter opening covered by one of the tested shields.	1) The most effective shield was the bili-mask
1991	Robinson et al [22]	1) Three eyepatches were measured by a Macam SR300 spectral radiometer in the wavelength range of 400-700 nm with a 10 nm interval. 2) The distance between the detector and the light source (Vickers Medical 80/885) was 350 mm.	1) Peak transmission (< 10%) was detected at 700 nm for the poorest patch and < 2% for either of the other examined patches. 2) The simplicity and effectiveness with which eyepatches could be secured may be as important as their transmission characteristics.
1993	Madsen [45]	1) Seven different types of eye shields used in the Danish NICUs were evaluated. 2) Ohmeda Phototherapy lamp 6000-0083-900 with a spectral output of 16 μw/cm^2/nm (in the 425-475 nm) was placed at a distance of 390 mm from a photographic light meter (Minolta Autometer IIIF) placed in an incubator.	1) A mask made of three layers of green cotton is sufficient for eye protection whilst Posey eye protector and a tube stockinette eye shields should be applied when using high intensity light phototherapy.

The above-mentioned research works examined the light transmission of EPs initially. The following limitations are identified:

(1) There existed large variations in the use of instruments for measurement. The measured range of wavelength and indices denoting the light intensity varied between different instruments. In some research works, the instruments and the

measuring index were inappropriate.

(2) The relationship between the neonate's eyes, the EP and the light source in these experiments did not mimic the clinical light condition so that could not really measure the effectiveness of eye protection offered by EP.

(3) Existing light transmission measurements of EPs focused mainly on the light transmittance characteristics of materials of eye-patch panels. Some researchers noticed that the transmission characteristic of materials is only one of the important factors for photo-protection of EPs. However, measurements taking other influencing factors into account, such as design for the level of fitting and security, are still very scarce.

2.3 Fabrication and Evaluation of Textile Materials

Textile materials and their end-products can protect human bodies from thermal, moisture, light, chemical harm and offer comfort and an intimate environment [46-48]. Functions, comfort and safety are three of the important requirements for textile materials and their end-products for neonates. The selection of textile materials affects the function, comfort and safety of textile products significantly [49]. Therefore, fabrication and evaluation of textile materials is the fundamental work for the development of an EP.

2.3.1 Textile Quality and Performance

Textile materials and clothing have been used since antiquity by human beings for the purposes of protection, comfort, and adornment [46]. The functional and comfort performance properties of textile materials are largely related to the fabric structure and the production process including fiber content, yarn count, fabric construction, fabric density, weight, and thickness [47, 50-52].

(1) Fiber content: Fibers are the primary material of which most textile products are made. Fibers are mainly divided into two types, natural and manufactured, and they contribute greatly to the fabric performance. They influence product durability, comfort, appearance, retention, care, environmental impact, and cost.

(2) Yarn count: Yarn is made up of long continuous strands and it is also the form of fibers for processes such as weaving, knitting, and lace-making. It contributes to the fabric and product performance significantly and affects appearance, drape, durability, comfort, and many other areas of performance.

(3) Fabric construction: Fabric construction formed of fabrication methods, such as weaving, knitting, and non-weaving contributes to fabric appearance, suitability for end-use, performance, and cost. Woven fabrics are produced by interlacing two sets of threads, namely the warp and weft, at right angles to each other. The basic woven fabrics include plain, twill, and satin, and their properties are firm, strong, good cover, compact, stable to stress, less air-permeable, less edge raveling, and usually light because less yarn is used. Knitted fabrics are made by interlocking a

series of loops from one or more yarn or even a set of yarn. They adapt easily to the body movement and are air-permeable, porous, less opaque, less stable for use and care, and usually heavy because more yarn is used. Non-woven fabrics refer to a fiber-web structure which includes all textile-sheet structures made from fibrous webs, bonded by mechanical entanglement of fibers, using resins, thermal fusion or chemical complexes. The properties of non-woven fabrics are various. The early goal of the non-woven industry was to provide non-durable and disposable products and therefore their significant advantage is inexpensiveness.

(4) Yarn density: Yarn density, namely fabric count, is the number of the warp and filling yarn per square inch of gray goods. It is an indication of the fabric quality. The higher the count is, the better the quality becomes.

(5) Weight: Fabric weight or fabric mass describes how heavy a fabric weighs for a given area or length of the fabric. It is crucial to identifying fabric appropriateness for end-use.

(6) Thickness: Fabric thickness is largely related to protective ability. The thicker a fabric is, the more effective the photo-protecting becomes.

2.3.2 Photo-protective Properties of Textile Materials

In this research, the primary function of the EP is to offer photo-protection on a visible wavelength. As textile materials and clothing are considered among the most effective and convenient tools for sun photo-protection [53-55], the photo-protection

characteristics of fabric materials are examined so as to select an appropriate material for the EP.

Factors affecting the fabric photo-protection ability include:

(1) Fiber content: Most research works concerning the influence of fiber content on photo-protection focus on the UV range. According to the results of some research works, untreated cotton, silk, polyamide, and acrylic fibers provide little absorption of the UV radiation. Polyester provides better absorption, especially on low wavelengths, whereas wool offers good absorption throughout the entire UV spectra [56, 57].

(2) Fabric structure: Fabric structures and product processes, such as yarn count, fabric construction, and fabric count, have major influence on porosity, weight, and thickness of fabrics. The density of a material is increased by increasing either the yarn count or the fabric count. Light fabrics with an open construction provide lower protection than compacted fabrics. The woven fabric is relatively stable with little stretch in the warp or filling. With a high fabric count, it provides maximum hiding power and cover. The knitted fabric is less stable for use and care, porous and less opaque. The non-woven (fiber-web) fabric is relatively stable with little stretch but its fiber distribution is not even and its density is relatively low, and as a result the cover ability is also relatively low [58, 59].

(3) Fabric dyeing: Color is an important parameter of reflection and transmission of visual radiation. The dyestuffs selectively absorb visible radiation in order to provide a color perception. Dyes are organic compounds that are able to

selectively absorb and reflect visible radiation. The color of a fabric is determined by the wavelengths it reflects, and this reflection in specific wavelength regions produces color. The amount of protection provided depends on the chemical structure of each dye as well as the dyeing intensity. In general, dark colors absorb more light than light colors [57, 58].

(4) Fabric finishes: Light-absorbing chemicals are added to fabrics during the production process and have impact on the photo-protective properties of fabrics. Thus far, there have been many research works conducted for UV protection [59].

(5) Product end-use: Photo-protection is provided by a product in the dynamic process, including stretching, washing, wearing, and wetting normally. These factors influence the effect of photo-protection. For example, photo-protection provided by a fabric reduces when it is stretched due to a reduction in the cover factor by enlargement of the holes in the fibers [52, 59].

2.3.3 Others Properties of Textile Materials

Protective textile products should not only fulfill the specific functional requirements but also meet all the textile product specifications in a single best design [60, 61]. Apart from photo-protection, other general properties of textile materials for neonatal products need to be evaluated as well. Table 2-3 shows the previous works of fabrication and evaluation of textile materials for neonatal products.

Table 2-3: Previous works of fabrication and evaluation of textile materials for neonatal products

Year	Researcher (s)	Product	Evaluated Properties
1992	Kwok [62]	Premature neonates' garments	1) Dimensional stability 2) Thermal-ability 3) Breathability (air permeability, water vapor transfer, etc.) 4) Safety (allergy, saliva test, colorfastness to crocking, flammability, static electrical charge test, etc.) 5) Durability (tear test, tensile strength, abrasion resistance etc.) 6) Handfeel (shear rigidity, residual shear angle, shear hysteresis, extensibility, tensile resilience, stiffness tester, compressibility, compressional resilience, surface contour, surface friction and roughness, etc.)
1996	Bergen [63]	Neonates' clothing	1) Thermal-ability 2) Comfort (soft, non-abrasive) 3) Safety
1999	Wong [64]	Child patients' garments	1) Physical property (thermal property, air permeability) 2) Durability to wear (tearing strength, tensile strength, abrasion resistance, seam strength) 3) Durability to laundering (colorfastness to washing, dimensional stability to washing, colorfastness to rubbing) 4) Safety (flammability, colorfastness to salvia) 5) Handfeel (surface property, bending property, compressibility) 6) Appearance (wrinkle resistance)
2001	Wong [65]	Child patients' garments	1) Thermal-ability 2) Air permeability 3) Handfeel (compression, surface, bending, etc.) 4) Durability (tensile strength)

For disposable EPs, dimensional stability and durability of materials are ignored in the evaluation of materials while thermal-ability does not need to be considered since warmth is not an aim of EPs and the covering area is limited [25, 66]. Thus, safety and physical/physiological comfort should be considered in fabrication of EPs [67-69]. The assessment methods of physiological comfort and safety for textile materials are shown in Table 2-4.

Table 2-4: Assessment of physiological comfort and safety on textile materials

Requirements of textiles for EPs	Subjective/objective measurements	Method/Instruments
Breathability		
1) Ability to transport air between the skin and the environment	1) Air-permeability	1) KES-FB8
2) Ability to transport moisture away from the skin	2) Water vapor transmission	2) ASTM E 96/E96M-05
Handfeel		
1) Ability to provide good handfeel without tickle, prickle and abrasion to skin	1.1) Subjective measurement	1.1) Survey
	1.2) Objective measurement	1.2) KES-F
	▪ Surface	KES-FB4
	▪ Bending	KES-FB2
	▪ Compression	KES-FB3
	▪ Tensile	KES-FB1
	▪ Shear	KES-FB1
Safety		
1) Ability to avoid allergy to skin	1) Allergy	1) Kwok
2) Ability to avoid burning	2) Flammability	2) ASTM D 1230-94

2.3.4 Systematic Evaluation of Textile Materials for Products

To meet the functional and general requirements for EP materials, a systematic evaluating approach must be adopted to select the most appropriate material for a single product. The following methods were applied to the systematic evaluation of materials.

(1) Each evaluated property was examined and then a fabric with more favourable properties for developing products was selected [70].

(2) A weight denotes the importance of a specific criterion while values were the objective measurement results. The total index of each evaluated fabric was calculated by Equation 2-1. The fabric samples with the highest total index were selected as materials for child patients' garments.

$$I = \sum w_i \times \frac{v_i}{m_i} \quad (2\text{-}1)$$

Where I is the total index of an evaluated fabric sample, w is the important weight of a specific criterion, v is the measured value of an property for this specific criterion, m is the mean of the measured values of an index for this criterion of all fabric samples [64].

(3) A weight denotes the importance of a specific criterion while a score is assigned to the material based on its ability to meet this criterion for each evaluation criterion. The total weighted score is calculated by Equation 2-2.

$$T = \sum w_i \times s_i \quad (2\text{-}2)$$

Where T is the total and weighted score, w is the weight of a specific criterion, and s is the assigned score based on its ability to meet this criterion. The fabric samples with the highest total index were selected as materials for child patients' garments [71].

Amongst above evaluation methods, weighting prioritization method described by Equation 2-2 can balance different evaluation criteria in a single material and compare evaluated fabrics using total weighted score. Thus, it will be applied in fabric evaluation for the new EP.

2.4 Anthropometry of Neonate

Anthropometry is a biological science of measuring size, weight and proportions of human bodies. It is the foundation of design and development of textile products for human beings [72]. In order to develop an EP that can shield the neonate's eyes securely, and fit different shapes and sizes of the neonate's heads, the dimensional characteristics of craniofacial morphology is essential. However, the anthropometric studies of neonates are very scarce and current works mainly focus on garment development [62]. Measurements taken in this research focus on the most sensitive areas of neonates — face and head, and the research has to be conducted in neonatal units. Therefore, the measuring instruments and methods must be extremely safe and portable while the measured subjects are not entirely cooperative. A sound review about anthropometric measurements of neonates is conducted to provide a foundation for selecting an appropriate measuring technology and conducting safe and accurate measurements for neonates.

2.4.1 Anthropometric Measuring Technologies for Human Being

In the early fifteenth century, Lenonardo da Vinci surveyed the human body to design the first articulated anthropomorphic robot [73]. Since then, different measuring techniques have been developed to meet the requirements for different applications.

(1) Manual Measurement：Tapes and calipers were used to obtain linear data

in the late 1800s and are still utilized now because manual measurement is simple and inexpensive. However, it is time-consuming, not often accurate, and involves high cooperation of the subjects needed [72]. Some measurements, such as those around the eyes, are difficult to obtain directly without risking discomfort or injury to the subjects. In addition, as manual measurement can be a contact method and most neonatal skin surfaces are soft and pliable, it is possible to deform the surface that leads to inaccurate measurement [74] .

(2) Sliding Gauge：A number of aluminium sticks of equal length are pushed smoothly towards the body surface and thus the curve connecting the points of the other ends of the sticks is traced on paper for further computation of body measurements and sectional areas. Bulkiness and clumsiness are the main disadvantages and the method demands high cooperation from the subjects [72].

(3) Physical Moulding：Liquid materials such as plaster are painted on the object to make an impression. When the material dries, information on the 3D shape can be copied as an inner part of the shell. However, the method is time-consuming and very expensive while the subjects have to be highly cooperative [72].

(4) Light Sectioning：A camera and a projector are employed in this method. The object is cast by a pattern projected by the projector and then photographed. Any point of light projected in a known direction by the projector and identified on the photograph can be positioned three-dimensionally. This technique is best suited to simple surfaces where cast lines are not interrupted [75, 76].

(5) Moire Topography：A camera, a grating and a light source are employed in

the Moire technique**.** 3D quantitative information can be obtained by Moire topography and the technique is widely applied to many fields, such as medical and clothing studies [72, 75, 76].

(6) Photogrammetry: It is a technique for obtaining information about the position, size and shape of an object by measuring its images instead of measuring the object directly [75].

(a) 2D photogrammetry: It is anthropometry adapted for quantification of surface features from standard photographs [77, 78]. The Silhouetter is also developed to capture 2D photographs of body contours with the background of a calibrated standard grid [72].

(b) Stereogrammetry: A stereo pair of photographs of the same object are recorded in two charge-coupled cameras which are placed at parallax angles [72, 79]. With the two photographs, it is possible to reconstruct 3D images of the objects. Stereogrammetry has been applied to medicine for diagnosing certain syndromes and clothing fields [79-85]. However, a single stereo pair of photographs can only provide accurate measurements of a single body surface such as the front aspect of a subject’s face.

(c) Multi-cameras Convergent Close-range Photogrammetry (CRP): The term “close-range photogrammetry” is used to describe photogrammetry when the extent of the measured object is less than 100 meters and cameras are positioned close to it. Photographs are

obtained from camera positions all around the object. Camera axes are usually highly convergent. To obtain information from a broad surface of the subject, a multi-station convergent imaging network is necessary [72, 86, 87]. Sometimes a projector is a component of this system to serve as a texture provider and a 3D contour of the object can be generated. Close-range photogrammetry is an effective measurement tool which has a number of advantages over alternative methods in terms of precise and reliable results. It is a non-contact method and gives quick data collection, a permanent image record, etc. Such systems are beginning to be developed for medical applications [88, 89].

(7) Laser Scanner and Infrared Scanner: The laser-based technology has been a key trend in 3D body scanning since the 1990s. Laser light is cast over the object, while the camera on the wand views the laser to record a cross-sectional profile of the object [72, 83, 90]. It measures the 3D shapes of the human body by positioning multiple distance sensors around the measured person. For live subjects, a disadvantage of both scanners is that the period of registration is relatively long and the subject cannot change its body position or facial expression over the whole period.

(8) Computed Tomography (CT) and Magnetic Resonance Imaging (MRI): CT and MRI are the most useful types of imaging modality for planning surgical management [91]. With the use of a rotating X-ray beam with detectors, cross-sections of the body can be registered by computed tomography. 3D images of

the structure can be reconstructed by selecting them on the slices and piling them up with the use of computer software. However, the accuracy of these images depends on the thickness of the original slices and the orientation of the object during the registration. Other disadvantages are the necessity of full co-operation of the subjects during the long scanning period and the relatively high radiation dosages. MRI makes use of strong magnetic fields to reconstruct 3D images of selected structures. MRI also requires full co-operation of the subjects though high radiation dosages do not apply to the technology [80].

The advantages and disadvantages of the above-mentioned anthropometric technologies are summarized in Table 2-5. Of all the techniques, photogrammetry, especially the multi-camera convergent close-range photogrammetry, offers a safe, environment-friendly, time-saving measuring method which is easy to operate.

Table 2-5: Comparisons of the anthropometric measuring techniques

Measuring techniques	Advantages	Disadvantages
Manual measurements	1) Easy to operate 2) Inexpensive	1) Time-consuming 2) High cooperation of subjects 3) Accuracy of data not guaranteed
Sliding gauge	1) 3D data	1) Bulkiness 2) Clumsy procedure 3) High cooperation of subjects
Physical moulding	1) 3D data	1) Time-consuming 2) Expensive 3) High cooperation of subjects
Light sectioning	1) Easy to operate	1) Only suitable for simple surfaces 2) Dark environment requirements
Moire topography	1) 3D data	1) Cannot obtain 360° 3D data at the same time 2) Bulkiness 3) Dark environment requirements
Photogrammetry	1) 3D data 2) Various assemblies are easy to set up 3) Time-saving 4) Easy to operate	1) Only multi-camera setting can obtain 360° 3D data
Laser/ Infrared scanner	1) 3D high-quality data	1) Expensive 2) High cooperation of subjects
CT or MRI	1) 3D data 2) Underlying hard tissues can be registered	1) Expensive 2) High cooperation of subjects 3) Time-consuming 4) Potentially dangerous

2.4.2 Anthropometric Measurements of Neonates

The whole or sections of the body were measured for many applications using various anthropometric technologies [62, 92-94]. For neonates, anthropometric measurements typically refer to gross measurements, such as body weight and length, limb length, chest, head, abdominal and limb circumference, obtained by manual methods [95]. Because of the critical requirements for safety and convenience for

neonates, very little has been done with respect to detailed measurement of newborns' eyes, ears and noses. It is noted that manual methods were used in anthropometric measurements of neonatal heads and faces for medical diagnosis [95]. In Figure 2-7, it is clearly shown that anthropometric measurement of the eye area using a caliper is extremely dangerous and accuracy of data is difficult to guarantee. Farkas *et al* reported that North American Caucasians from birth (one year) to young adults were measured by manual methods. Among the subjects, there were eight neonates of 0 to 5 months old. The anatomical region involved heads, faces, noses, ears, lips, and mouths using the photogrammetric method [78].

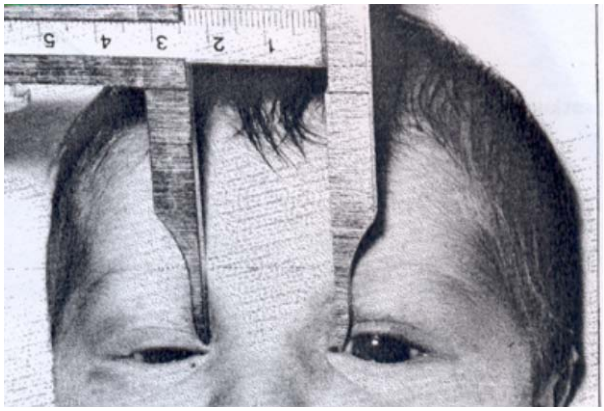


Figure 2-7: Manual measurement of neonates by caliper

2.4.3 Anatomical Landmarks on Head and Face

The definition and identification of anatomical points as landmarks for anthropometric measurements are essential for the reliability of measurement and special requirements for some measuring methods such as photogrammetry. In photogrammetry, landmarks must be put carefully on the measured subject as

"coordinates" before taking pictures. In 1994, Farkas established a system of landmarks to measure the head and face with 6 landmarks on the head, 6 landmarks on the face, 8 landmarks on the orbits, 11 landmarks on the nose, and 8 landmarks on the ears. Those landmarks are shown in Figure 2-8. In the upper figures, the landmarks are marked on the skin of the subject. The lower figures show the surface landmarks in relation to the underlying craniofacial skeleton [78]. And details of these landmarks are presented in Table 2-6.

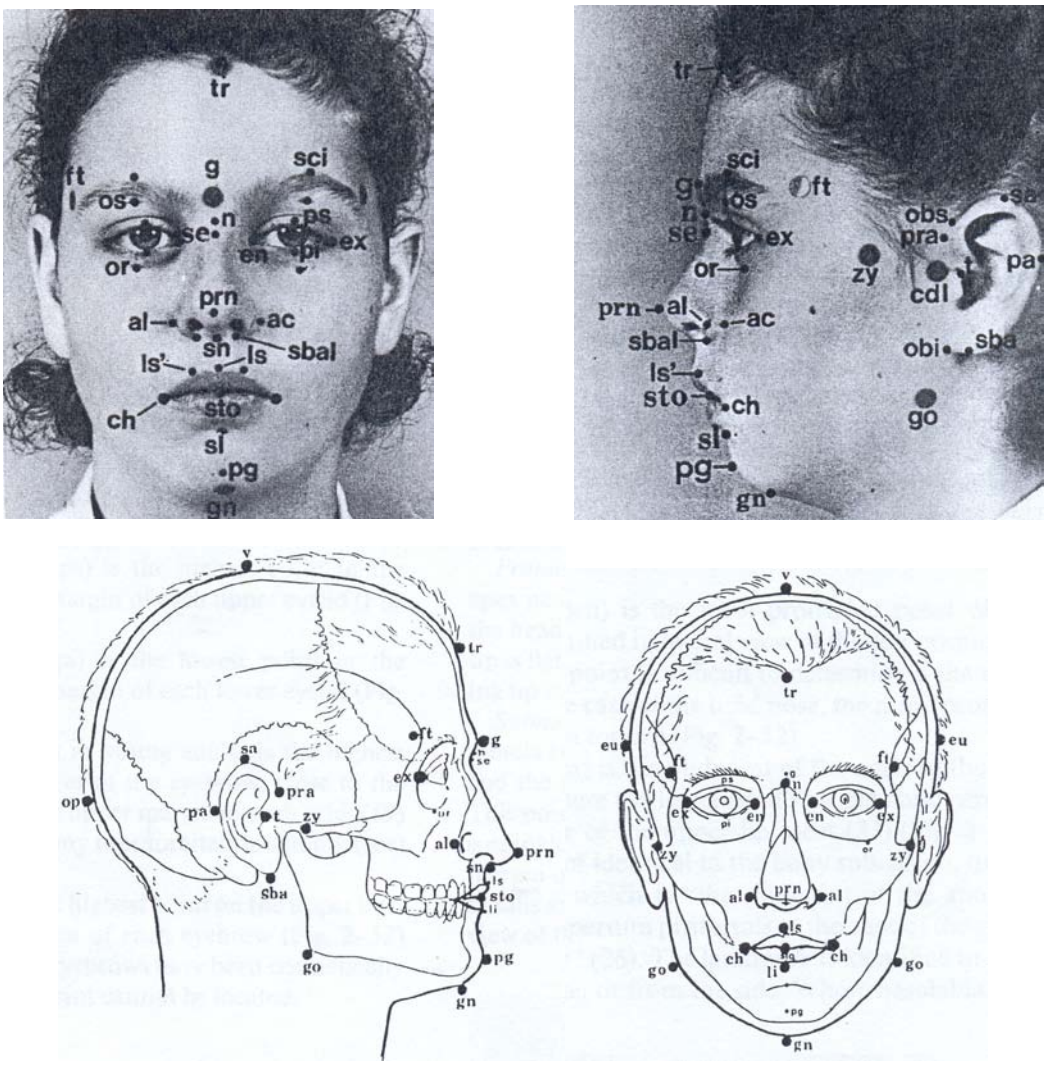


Figure 2-8: Craniofacial surface landmarks in frontal and lateral aspects

Table 2-6: Farkas' landmarks system related to craniofacial morphology

Locations	Landmarks	Abbreviations
Head	1) Vertex	1) v
	2) Glabella	2) g
	3) Opisthocranion	3) op
	4) Eurion	4) eu
	5) Frontemporale	5) ft
	6) Trichion	6) tr
Face	1) Zygion	1) zy
	2) Gonion	2) go
	3) Sublabiale	3) si
	4) Pogonion	4) pg
	5) Menton	5) gn
	6) Condylion laterale	6) cdl
Orbit	1) Endocanthion	1) en
	2) Exocanthion	2) ex
	3) Orbitale	3) or
	4) Orbitale superius	4) os
	5) Palpebrale superius	5) ps
	6) Palpebrale inferius	6) pi
	7) Superciliare	7) sci
	8) Center point of the pupil	8) p
Nose	1) Nasion	1) n
	2) Sellion	2) se
	3) Maxillofrontale	3) mf
	4) Alare	4) al
	5) Pronasale	5) prn
	6) Subnasale	6) sn
	7) Subalare	7) sbal
	8) Alar curvatura point	8) ac
	9) Highest point of the columella	9) c'
	10) Alare'	10) al'
	11) Subnasale'	11) n'
Ear	1) Superaurale	1) sa
	2) Subaurale	2) sba
	3) Preaurale	3) pra
	4) Postaurale	4) pa
	5) Otobasion superius	5) obs
	6) Otobasion inferius,	6) obi
	7) Porion	7) po
	8) Tragion	8) t

A set of appropriate landmarks will be chosen from above landmarks system

according to morphologic characteristics of EP.

2.5 Protective Textile Product Design and Development

2.5.1 Research Works of Protective Textile Product

The need of textile products for special purposes, such as medical use, sports activities, industrial use, and energy conservation, has been growing rapidly in recent years [48]. Some successful research works include:

(1) Products which aim to protect people from diverse sources of mechanical nature, chemical nature, electromagnetic origin, microbiological origin, and extreme climate [96], such as firefight clothing [97], surgical gowns [97, 98], flight-suits [99], and artificially-cooled gloves [100].

(2) Products for people with special physical or/and physiological characteristics, such as clothing for neonates [62, 63, 101, 102], clothing for people with physical disabilities [103], underwear for individuals suffering from inflammatory bowel diseases [104].

(3) Products for people whose action is over the normal range, at stressful strength and/or at a high level of frequency, such as work clothing for pear farmers [105], and shoes for sport climbing [106].

For neonates in the most vulnerable period of their life, textile products help develop a microclimate of comfort and protection. Kwok developed garments for premature neonates to wear in a hospital environment [62]. Bergen *et al* designed

diminutive-size clothing for neonates in light weight [63]. Howsden invented a neonate-care garment for immediate or intensive care [102]. Ray invented comforting clothing for four-month-old newborns with developing nervous systems exhibiting a “Startle” or “Moro” reflex [101]. These research works accumulate practical experiences of design, development and evaluation of textile products for neonates and develop an appropriate methodology for further research. Though these studies of textile products for neonates, they are restricted to thermal clothing development.

2.5.2 The Product Design and Development Model

The definitions of design are diverse and they range from scientific to artistic. Koberg and Bagnall defined that design is a highly organized mental process capable of manipulating many kinds of information, blending them all into a coherent set of ideas, and finally realizing those ideas [107]. And Lawson suggested that design is the optimum solution to the sum of the true needs of a particular set of circumstances [108]. The above-mentioned definitions of design can be applied to protective product development.

Product development is a complex process which involves many organizational units and engineering disciplines. Each product development process is unique, but all processes share common features or elements. The goals of process modeling are learning about the process and suggesting ways of controlling the process. A number

of models of product design and development are presented as follows.

2.5.2.1 The Product Development Process Model

As design is a plan for making changes, creativity and logical thinking are essential, by brainstorming ideas from different fields, and using a logical flow to narrow down the ideas and to focus on problem-solving [109]. The design process is a sequence of events, which requires creative behavior from its participants, improves current conditions, and finds ways out of dilemmas [107]. Since effective design and development of protective products require consideration of an extensive number of requirements and a broad range of expertise, a protective product design process is the key to a successful launch of protective textile products [61, 110]. Koberg and Bagnall developed a general design process which extracts the essential characteristics of many specific problem-solving processes [107]. Watkins refined Koberg's process to develop an apparel design process [111]. Orlando developed a protective apparel design model which was adapted from the specific stages of Jones' design method, including divergence, transformation, and convergence [60, 112]. In Orlando's model, a protective product development process includes the following stages: request made, design situation explored, problem structure identified, design criteria established, specifications described, prototype developed, and design evaluated (see Figure 2-9). However, elements and structures of the design process of different protective product developments may vary according to the nature of the problem being tackled.

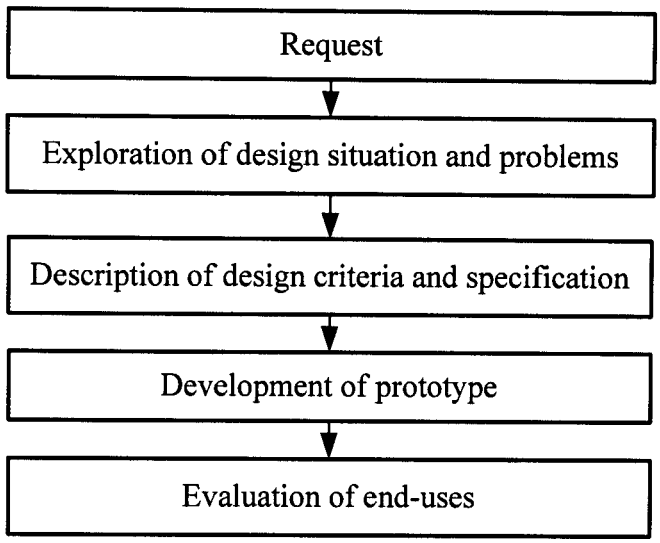


Figure 2-9: Product development process of Orlando's model

2.5.2.2 Analysis of Interconnected Decision Areas (AIDA) Model

The Analysis of Interconnected Decision Areas Model (AIDA Model) originated from a study of building history design study undertaken as part of research at the Institute for Operational Research [113]. The model was then extended to other fields such as engineering design, city planning, and modeling and implementing creative design by computer [114-119].

The AIDA is a unique technique that can be used to show interdependencies and relations between decisions specifically, which makes the AIDA a powerful tool for defining the solution space, especially when there is a multitude of seemingly independent, yet interrelated, decisions that designers face. The advantage of this model is that it describes a useful set of knowledge concerning a design process with many interrelated design subcomponent decisions. The disadvantage is the lack of application in the literature. It may be because the amount of predictive knowledge of

whether certain sub-solutions are incompatible exceeds the amount available at the time when decisions are made, or that collecting this information is prohibited [120-122]. The framework of the AIDA model with six stages is shown in Figure 2-10.

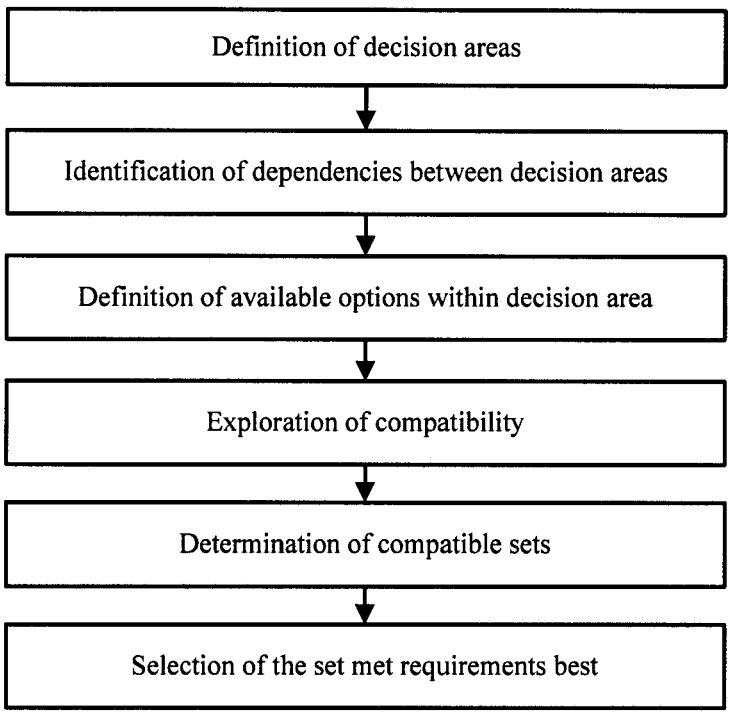


Figure 2-10: The framework of AIDA model

2.5.2.3 Other Models

(1) Petri net model

This model describes the information flows in engineering using a Petri net. The main advantage of Petri nets is the handling of concurrent and iterative e-flows. The disadvantages include no weighting to the connections, a lack of useful measures of time, and the emphasis on feasibility as the outcome measure of rest [123].

(2) Design sequences models

These models acknowledge that design is constituted of a number of decisions, and each decision alters the decision space available for future decisions. These models seem a good way to describe design processes after they have occurred. But it is used for retrospective description and not as a predictive tool [124-126].

(3) Time-related models

The lead time of product development is one of the critical factors in success. Many process choices affect the lead time and time is inherently quantifiable. There are many models for which time is one of the dependent variables of interest, such as sequencing and scheduling models [127-130], decomposition model [131-134], stochastic lead time model [135, 136], design review timing model [137-140], and parallelism model [141-143].

Amongst above-mentioned design model, Orlando's model can provides a basic framework of the new EP developing process. And AIDA is considered as a useful technology for solving comprehensive problems in a single product design to meet special criteria such as function and safety, etc.

2.6 Problem Statements

Based on the extensive literature review shown above, the following knowledge gaps are identified:

(1) Craniofacial measurements of neonates are the foundation of EP pattern construction, development of a sizing system and a neonatal head model. However,

anthropometric data of neonatal craniofacial morphology are scarce. There is no report about craniofacial measurements of neonates in Hong Kong which can be applied to the development of EPs. Furthermore, the current measuring system cannot meet the critical requirements for safety, data quality, comfort, environment compatibility, and psychological acceptance. Therefore, an anthropometric measuring system for neonates in hospital approved by the medical staff needs to be developed, and anthropometric measurements of neonatal craniofacial morphology need to be conducted.

(2) The research works about photo-protection of textile materials under high-intensity visible light conditions are limited. The general requirements for neonatal textile products, such as comfort and safety, also need to be considered for the fabrication of materials for eye-patch panels. A systematical evaluation approach needs to be developed for selecting appropriate textile materials and fixing systems for the new EP.

(3) In most of the previous works, measurement of photo-protections of EPs focused on material characteristics. However, these evaluations were not comprehensive because some factors, such as design, also affect photo-protection considerably. In the pilot studies aimed at a comprehensive evaluation of photo-protection of EPs, the light and EP setting could not mimic the clinical light situation and the EP wear condition on the neonate’s head. A simulated clinical environment needs to be set up so as to mimic the clinical phototherapy environment with various assemblies of light source (i.e. light units, tubes permutations, locations,

directions, and distances). And the practical effects of eye protection provided by EPs in optimum and displaced positions need to be evaluated to identify the photo-protecting ability of EPs while the security of EPs also needs to be identified in the wear trial.

(4) Some product development processes have been developed in many research works. However, data on the product development model of protective products for neonates are still limited. The product development model needs to be formulated for offering guidelines on further protective product development.

The above knowledge gaps are the indispensable elements of EP development and are studied in this research.

CHAPTER 3: EXPLORATION OF DESIGN CRITERIA AND SPECIFICATIONS OF NEW EPS

3.1 Introduction

Based on the problems of the current EPs and the research gaps discussed in Chapter 2, the design criteria and specifications of the new EP (EP_n) are discussed in this chapter. Figure 3-1 presents the three stages of the product development process involving “request”, “exploration of design situation and problems” and “description of design criteria and specification”. In this study, explorations of design situations and identifications of problem structures were conducted by field observation, focus group interviews, and questionnaire surveys. Based on the results obtained from the above-mentioned stages, the design criteria and specifications were identified for the development of EP_n.

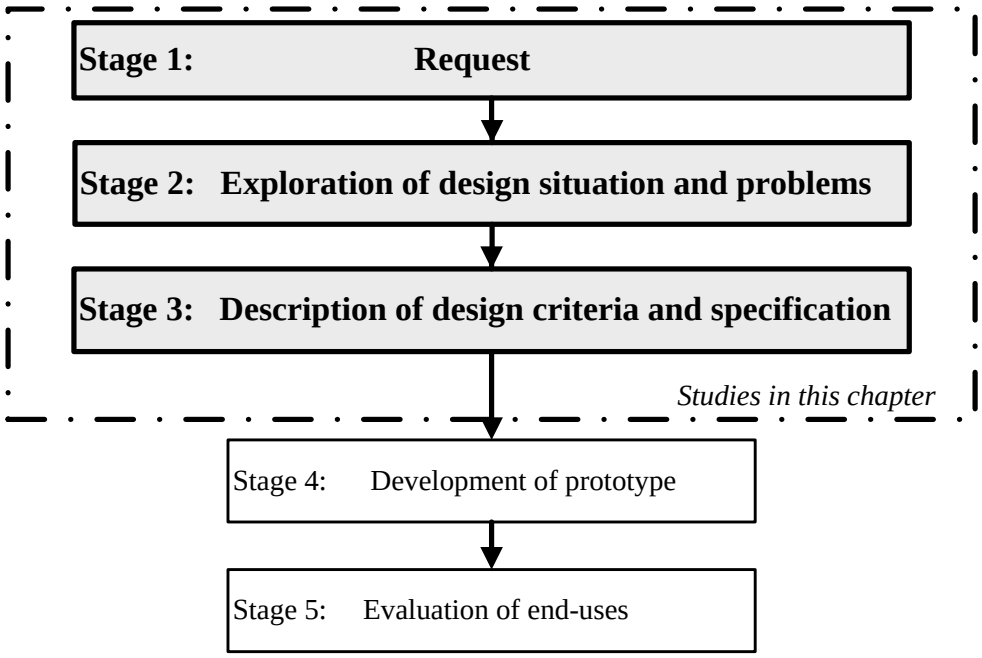


Figure 3-1: Stages 1-3 of the protective product development process

3.2 Field Observation in Queen Mary Hospital

Field observation is indispensable and the most effective way to explore the design situation thoroughly. The purpose of field observation is to identify the factors affecting the use of EPs and the clinical practice of the hospital.

3.2.1 Hospital Environment

Queen Mary Hospital (QMH) was established in 1937. It is a public hospital in Hong Kong, China, providing medial services to a population of over 1.2 million on Hong Kong Island. It is also a teaching hospital for the Li Ka Shing Faculty of Medicine of The University of Hong Kong, undertaking an important teaching role for undergraduates and postgraduates in medical, dental and nursing professions. The

Department of Paediatrics and Adolescent Medicine at QMH is committed to the provision of patient-centred, seamless, comprehensive, and quality services to children. There are two units — neonatal intensive care unit (NICU) and special care baby unit (SCBU)，admitting neonates who require observation and/or treatment. The NICU admits the very ill neonates whilst the SCBU admits those who need special care and treatment, such as neonatal jaundice. In this study, all clinical activities, including field observation, interviews, and surveys conducted for the medical staff, fabric allergy tests, experimental evaluation of photo-protection of EPs, and wear trials, were conducted in the SCBU which is on the 10th floor of North Part of K Block (K10N) at QMH (see Figure 3-2).

Figure 3-2: Scenes of routine practice in the SCBU of QMH

Generally, the hospitalization period of neonates being transferred and admitted to the SCBU is relatively short, ranging from 1-2 days to less than 10 days. The hospitalization period of jaundiced neonates is normally within a week. In the SCBU, some neonates are in need of the special skills of highly trained nurses and pediatricians, and they make up a large part of the work of the neonatal units [28].

Furthermore, the routine care for neonates, such as feeding, increases the workload of the SCBU staff heavily.

Figure 3-3 presents a floor plan of a typical ward in the SCBU. The field observation shows that the space in the SCBU is limited. All incubators and cots are portable to facilitate the safe transfer of neonates. All the equipments including desks and chairs are easy to sanitize and convenient to operate.

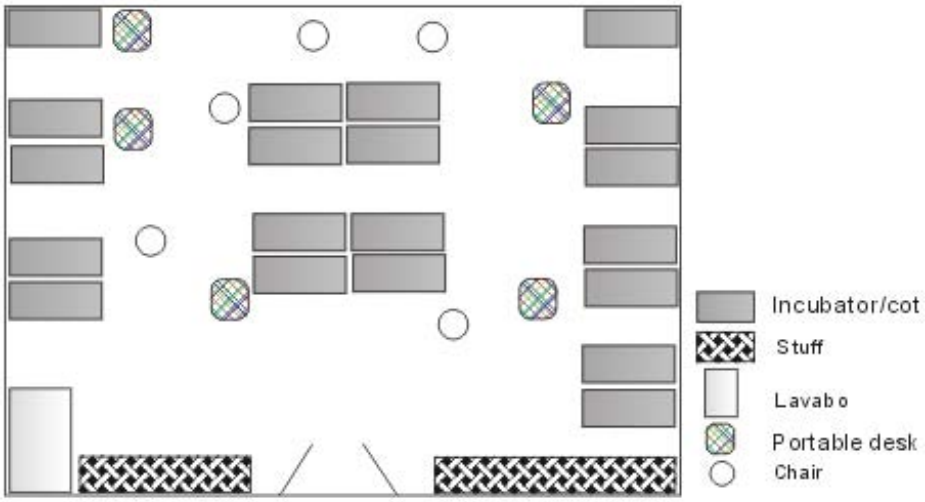


Figure 3-3: The ichnography of typical ward in the SCBU of QMH

3.2.2 The Term Neonates

According to gestation, neonates born before the 37th week of pregnancy are considered pre-term or premature while those after the 37th week are full-term [144]. Theoretically, both pre-term and full-term neonates are possible to be infected with neonatal jaundice. However, pre-term neonates are immature and some body systems are not ready to take on the various functions and activities necessary for a healthy

survival. Under this condition, it is not advisable to conduct unnecessary tests and/or trials for this group of neonates. Thus, full-term neonates were designated as subjects of this research and all studies related to EP_n development were carried out with the consent of their parents or guardians. The study was also reviewed and approved by the Institutional Review Board of The University of Hong Kong of Hospital Authority Hong Kong West Cluster.

3.2.3 Phototherapy Unit and Its Assembly

There are three types of phototherapy units used in QMH, namely Medela® fluorescent phototherapy unit, Ohmeda® BiliBlanket, and Ohmeda® halogen spotlight unit. Generally, the Medela® fluorescent phototherapy unit and the Ohmeda® BiliBlanket are used in the NICU and the SCBU alike. However, the Ohmeda® halogen spotlight unit is used in the NICU only because it is fixed on a neonate warmer system which is located in the NICU. The Ohmeda® BiliBlanket is a fiberoptic pad with a light source of high-intensity halogen bulbs. The pad is placed in direct contact with the trunk of neonates because it emits an insignificant level of heat, and it is therefore not necessary to cover the neonate's eyes. Thus, the Medela® fluorescent phototherapy unit is the main light source in this research.

The Medela® fluorescent phototherapy unit consists of four compact fluorescent tubes. Blue, white or mixed light can be chosen if needed. Blue light may be the most therapeutic for jaundiced neonates, but various "irritations" have been reported when

using the blue fluorescent tube, such as headaches, nausea, and vertigo [145]. Similar complaints from the medical staff have also been reported at the SCBU. Therefore, based on the needs of the neonates and clinical practice, four mixed tubes of blue and white lights and four blue tubes are frequently used.

As effective phototherapy is very much dependent on the exposed body surface area, the neonate is naked in the incubator during phototherapy treatment [146]. In the SCBU, the standard Air Shields Isolette Incubator with a height of 400 mm is used. Considering a distance of 50 mm from the light to the roof of the incubator for thermal safety, the available distance between the light and the mattress in the incubator is 450 mm for the most effective treatment. This distance is applied to many related research works [10, 36]. The geometrical setting of the light unit, the incubator, and the neonate is shown in Figure 3-4.

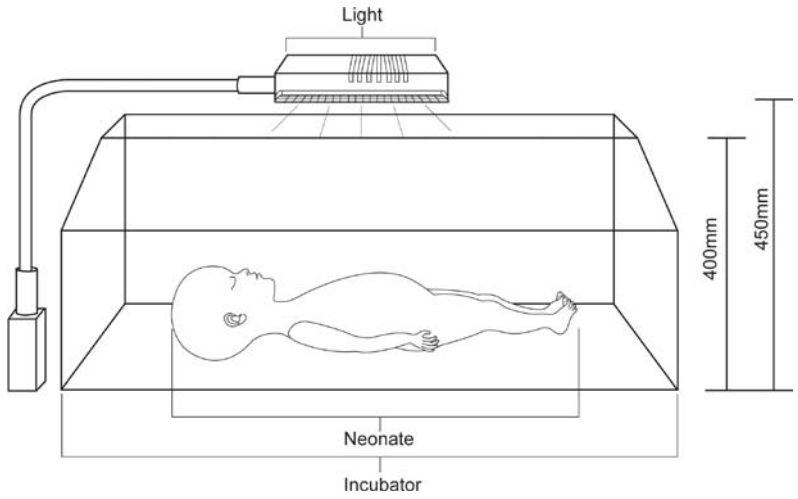
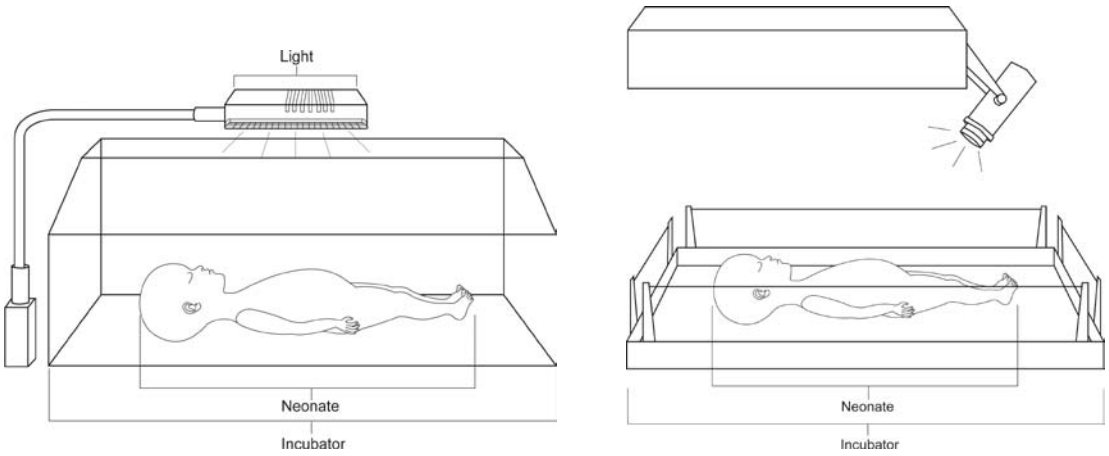


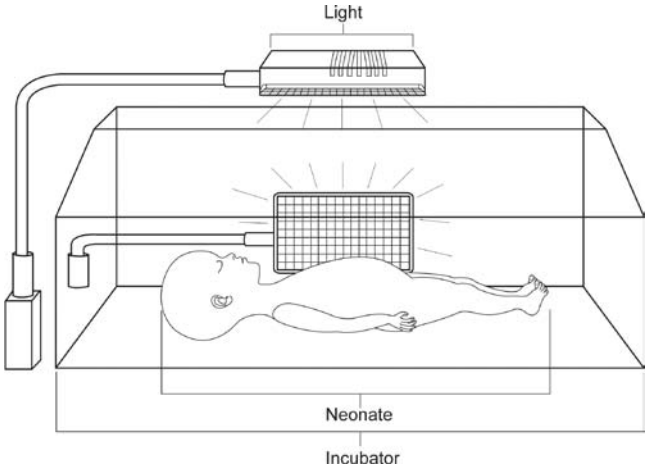
Figure 3-4: Geometrical setting of light unit, incubator and neonate

The settings of units are classified as single, double and triple in clinical pracitice as shown in Figure 3-5.

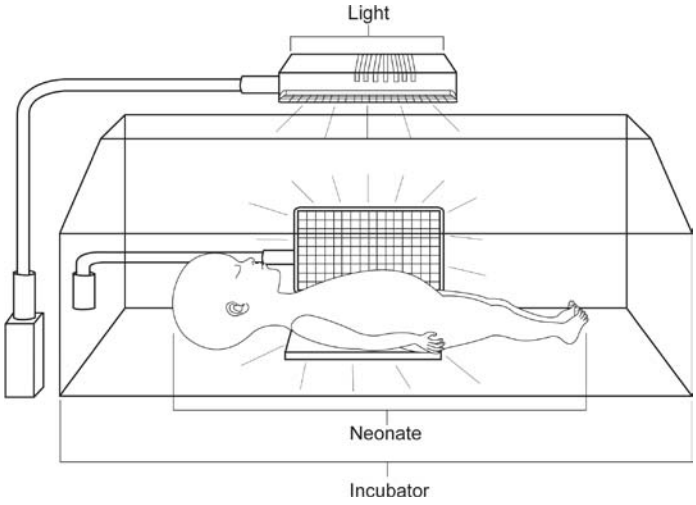


Fluorescent Iight Halogen Light

(1) Single unit



(2) Double unit



(3) Triple unit

Figure 3-5: Typical ways of assembly of units in the SCBU

In clinical practice, for usual-size term neonates, phototherapy treatment is conducted when (1) bilirubin level >= 250umol/L after completion of 3 days, and (2) for neonates less than 3 days of life (72 hours of life); phototherapy treatment is conducted according to different levels at different hours of life. The guide to phototherapy treatment is shown in Figure 3-6. Triple phototherapy for severe jaundice is carried out especially when the level is close to that of exchange transfusion (~ 340 μmol/L after completion of 3 days, a lower level when < 72 hours of life). Double phototherapy is halfway for the treatment of moderately severe jaundice.

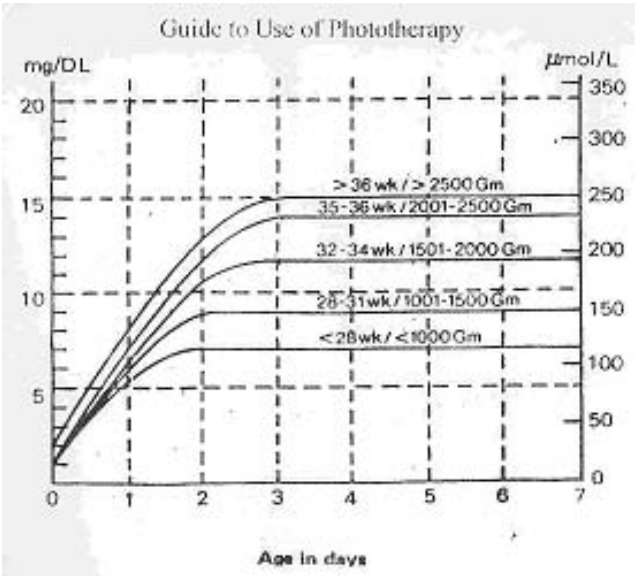


Figure 3-6: Guidelines on phototherapy application

3.2.4 Practice of Care and Treatment

The daily practice of care and phototherapy treatment for neonates is shown in Figure 3-7. A senior paediatrician leads a group of paediatricians for examination,

observation, and discussion on each neonate at 10:30a.m. and 5:00p.m. each day. The treatments are conducted by the paediatricians before or after the examination.

Nurses' work consists of observation, changing linen and nappies, monitoring the neonate's temperatures, feeding, and giving simple treatment to the patients. Of all duties, feeding is one of the most important care practices for neonates. Feeding at three- or four-hour intervals is determined by the medial staff according to the neonate's weight. The phototherapy unit is turned off and the EP is removed from the neonatal head by the medical staff before feeding. After feeding, the medical staff checks the sanitary condition of the EP to decide whether a new/clean EP is needed. After securing the EP to an optimum position of the neonatal head, the phototherapy treatment continues.

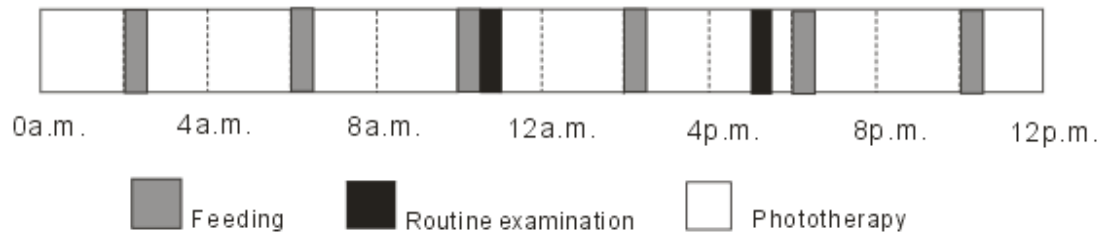


Figure 3-7: Routine practices of care and medical treatment

3.2.5 Current EPs Used in QMH

3.2.5.1 Posey® Phototherapy Eye Protector

As recommended by the US National Research Council in 1974, the neonates' eyes must be closed and shielded during phototherapy and EPs have since been used in neonatal units routinely [44]. A mass of commercial and home-made EPs are

developed to offer eye protection all over the world.

In Hong Kong, a commercial EP, Posey® phototherapy eye protector from the USA, is currently used in QMH. Prior to the adoption of commercial EPs, home-made EPs with a two-layer black twill cotton fabric were used in the hospital. The home-made EPs can be cleaned and re-used like cotton sheets, whereas most of the commercial EPs are disposable. In the following sections, the Posey® phototherapy eye protector is abbreviated as "EP_1".

The specifications of EP_1 are shown in Figure 3-8. It consists of two panels: an eye-patch panel to protect neonatal eyes from strong light and a fastening panel to fix the eye-patch panel to an optimum position of the neonatal head. The eye-patch panel is shaped as two-crossed rounds by a composite with an inner layer of 100% white cotton-knitted fabric, a middle layer of grey open cell foam, and an outer layer of white nylon loop fabric. The fastening system consists of a top band and a back band. Two branches of the back band in a rectangular shape extend from the eye-patch panel directly. An elastic band and a hook are fixed to the end of the right foot of the back band. The top band is sewn onto the center of the left back band by a loop material while a hook is sewn onto the center of the right back band for matching the hook.

A gauze layer is added to the EP_1 by the local medical staff and is replaced every day to save costs.

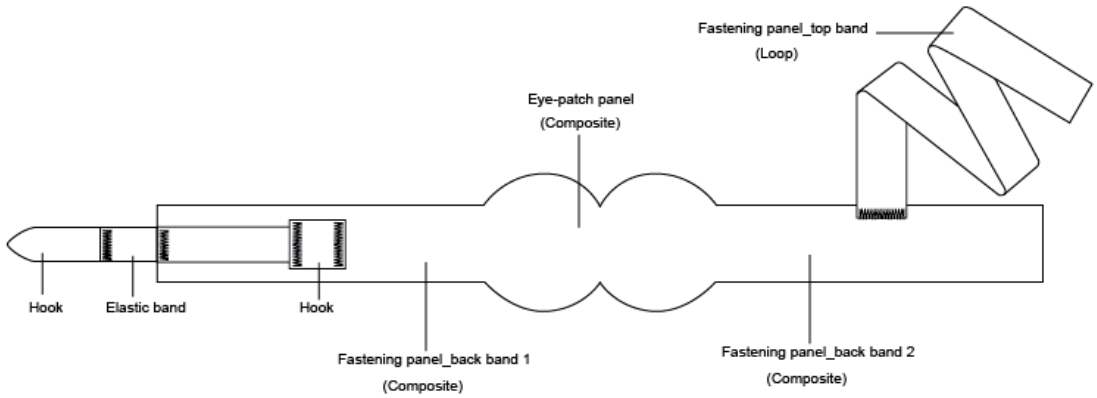


Figure 3-8: Specifications of Posey® Eye Protector (EP_1)

3.2.5.2 Biliband® Phototherapy Eye Protector

More recently, a new commercial EP, the Biliband® phototherapy eye protector made in USA, has been used in QMH on a trial basis. Some useful information of the eye protector will be identified for reference in this research. In the following sections, this eye protector is abbreviated as "EP_2".

The specifications of EP_2 are shown in Figure 3-9. It consists of an eye-patch panel and a fastening panel. The eye-patch panel is in an orbit shape using a composite with an inner layer of 100% blue cotton knitted fabric, a middle layer of black foam, and an outer layer of 100% black cotton knitted fabric. The fastening panel is a wide band with two branches using a crumpled non-woven fabric. One branch of the back band covers the eye-patch panel and the other covers the forehead of the neonate's head. Both of them are fixed to a symmetrical line.

In this study, EP_2 also serves as a reference for the design and development of EP_n. Nevertheless, it is noteworthy that EP_2 is only used for fabrication, style design, and wear trials as it is introduced to QMH at the end of this study.

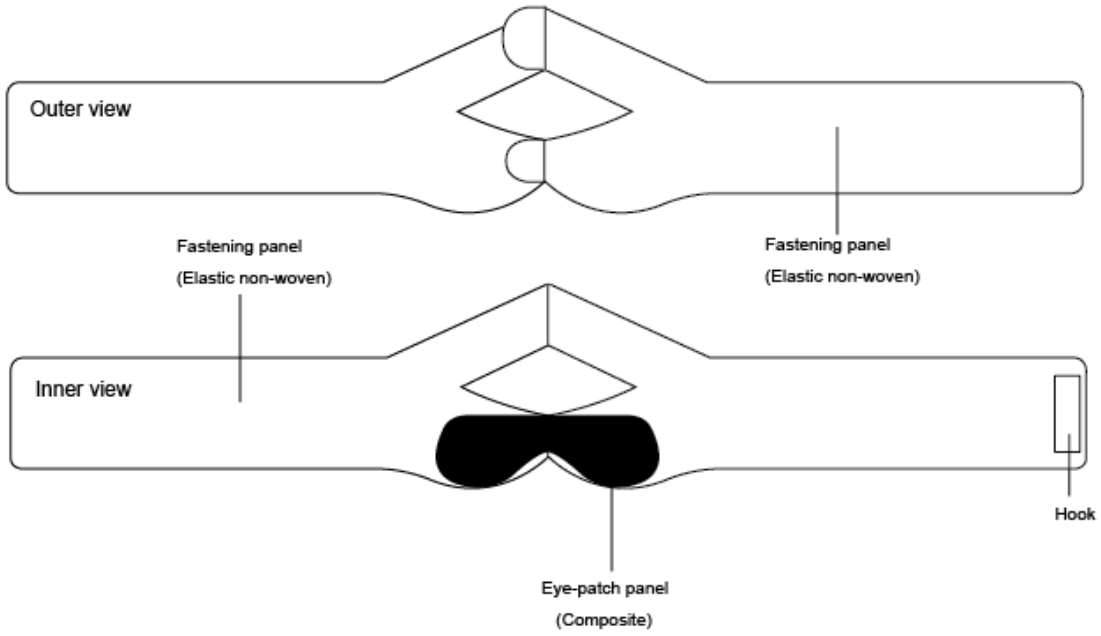


Figure 3-9: Specifications of Biliband® Eye Protector（EP_2)

3.3 Focus Group Interview and Questionnaire Survey

Focus group interview is one of the most common techniques for new product development studies to assess consumers' reaction to a product [147]. Questionnaire survey can obtain accurate data about facts, comments, and attitudes from the respondents in a standard format [148, 149]. These two methods aim to identify the problems of EPs, the requirements and recommendation for a new EP development. Based on the qualitative and quantitative results, design criteria and specifications of developing a new EP can be established.

3.3.1 Focus Group Interview

In this study, the focus group interview was conducted in the SCBU of QMH. Eight medical staff were involved as they are caregivers of the neonates, and the neonatal end users are not capable of giving comments on the EP. The evaluated EP is EP_1. The key comments are presented as follows.

"Displacement of the EP happens frequently when the neonates move a lot during phototherapy. Apart from causing possible eye damage, reposition of displaced EPs not only increases our workloads but also disturbs the neonates."

"The shape of the neonate's head has been changing during the first few days of life because it is "molded", especially the birth process when the head is elongated. It is difficult for the current EPs to fit various head morphologies."

"There are light gaps when the EP is in optimum and displaced positions."

"When we try to bind the EP tightly to keep it in place, it may cause bruises around the babies' eyes."

"The gauze can keep the good sanitary condition of the EP. However, it is sometimes too rough for the neonate's eyes."

"It is difficult to select appropriate EPs for neonates with a very large or small head circumference."

The results of the focus group interview show that negative comments of EP_1 focused on security, fitting of EPs, comfort of materials, safety, and the sizing system whilst positive comments mainly focused on donning/doffing and appearance. Amongst the negative comments, security (i.e. displacement) is the most serious problem of EP_1. Head morphology variations and head movement variations are two of the main causes of this problem. The back band is easily moved by connecting and rubbing the cot or pillow. The top band is difficult to locate in an optimum position because of variations in the head circumference. The thick composite of back bands is too stiff to fix an eye-patch panel in place even by applying pressure.

The light gaps of the EP are observed even though EP_1 is in an optimum position. One of the reasons causing the light gaps is that the style design of the eye-patch panel in a geometrically round shape cannot match the morphology of the neonatal face perfectly. The composite of the eye-patch panel can implement multi-functions, such as photo-protection, comfort, and fastening, but it is too thick to match the complex morphology of the neonatal face. The gauze layer may enlarge the light gap although it helps the sanitization of the EP.

The highly stiff composite may cause irritation to neonatal eyes. Moreover, the gauze layer worsens the comfort condition of the EP_1. The sizing system fails to cover all neonates.

3.3.2 Questionnaire Survey

The questionnaire survey was conducted in the SCBU of QMH. 42 medical staff members, including doctors, nurses, and health care assistants, were invited to fill in the survey. The questionnaire was designed based on the results of the focus group interview with a 5-point scale. The score assignment and denotation for each scale are as follows: 5-Extremely Acceptable, 4-Acceptable, 3-Neutral, 2-Unacceptable, and 1-Extremely Unacceptable.

EP_1 was evaluated in terms of 1) sizing, 2) fitting, 3) security, 4) safety, 5) applicability of treatment/care, 6) comfort; 7) donning and doffing , 8) use of gauze, and 9) appearance. A summary of the results is presented in Figure 3-10, and an error bar plot which presents the mean and standard deviation of each of the evaluated items is shown in Figure 3-11.

EP_1 offers three sizes, 4646 for the term baby whose head circumference is in the range of 310-350 mm, 4645 for the premature baby whose head circumference is in the range of 230-340 mm, and 4644 for the small premature baby whose head circumference is in the range of 300-240 mm. 50% of the respondents disagree that the size specifications of two EP_1s can cover all neonates (with a mean score of 3.00).

Most of respondents believe that EP_1 does not fit the neonate craniofacial morphology (with a mean score of 2.76). It is difficult for an eye-patch panel in a planar shape to fit the complex craniofacial morphology, especially the nose part.

About 74% of the respondents disagree that EP_1 can be held in its optimum position securely. It produces a mean score of 2.21, which is the lowest among the

evaluated items, and shows that security is regarded as the most serious problem of the current EPs. In this study, the effects of both style design and materials used are examined carefully for the development of a new EP.

About 17 % of the respondents agree that EP_1 is safe (with a mean score of 2.71). The harmful aspects mainly concern bruises around the neonates' eyes caused by tight binding, irritation or rubbing of the eyelids, and corneal abrasion caused by the rough gauze.

Most of the respondents agree that EP_1 does not make other medical treatments/cares difficult except the practice of the CPAP system (it is a kind of non-invasive ventilation that provides constant positive pressure to help distend the baby's lung with thick tubing extending to both sides of the face).

Most of the respondents agree that the materials used for EP_1 are comfortable, and they accept the use of gauze (with mean scores of 3.26 and 3.69). The use of knitted fabric as the inner layer of the composite and the loop tape of the top band is perceived to be comfortable for neonates.

Most of the respondents agree that EP1 is easy to don and doff (with a mean

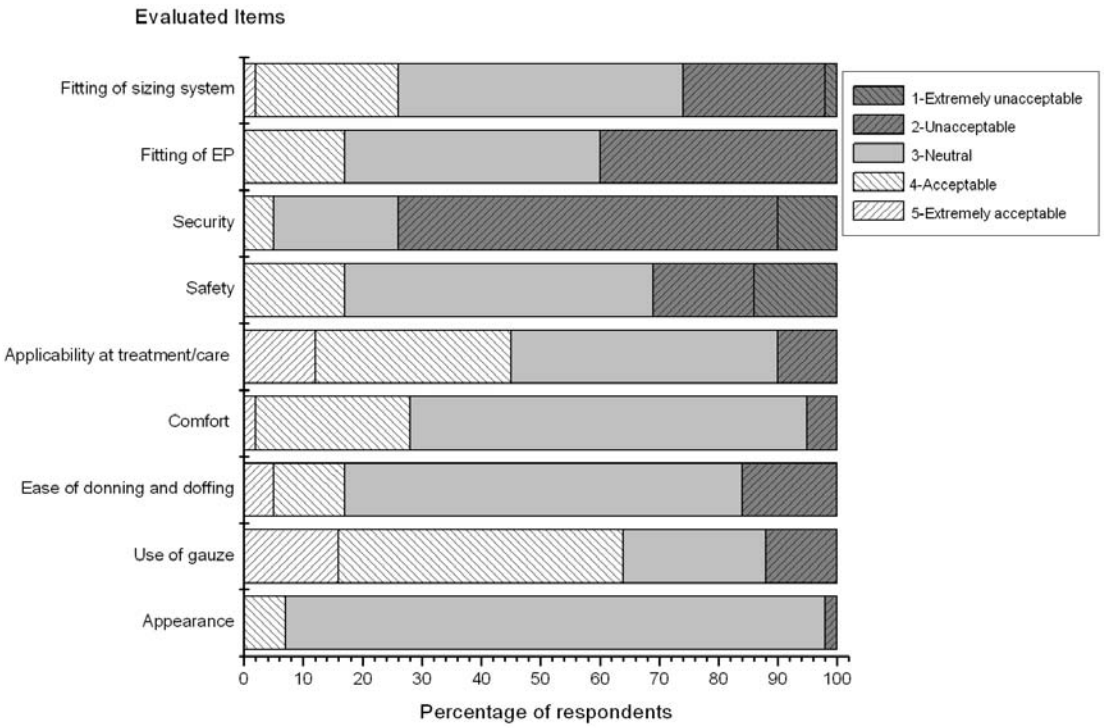


Figure 3-10: Questionnaire survey results of EP_1

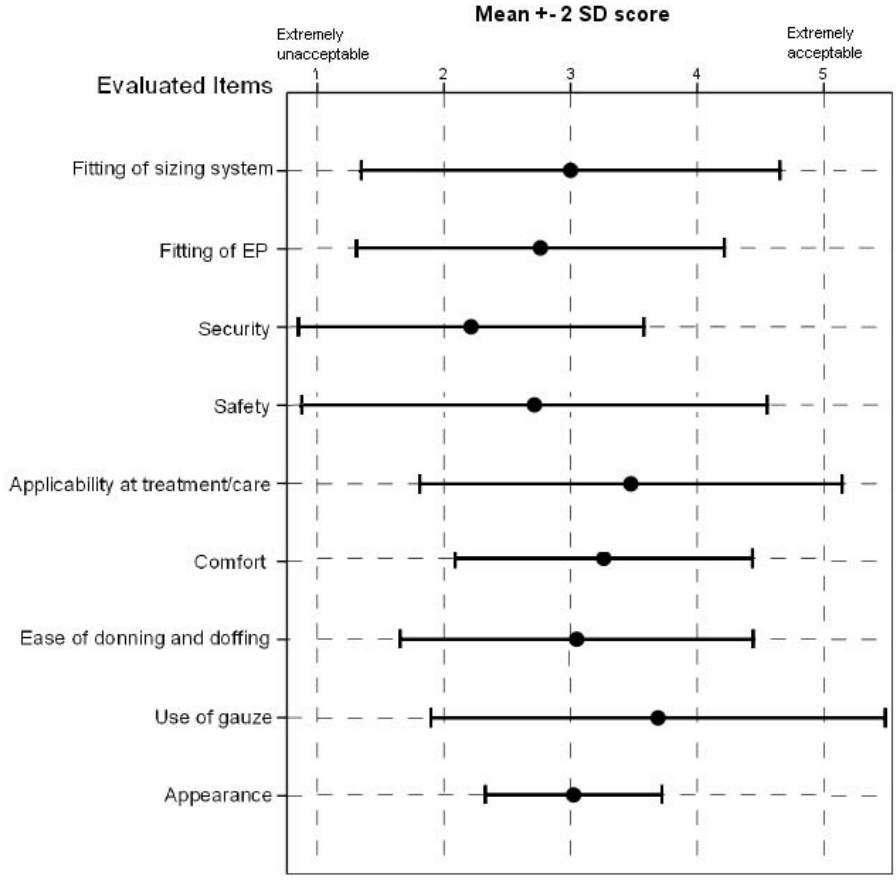


Figure 3-11: The error bar plot of the survey results of EP_1

score of 3.05). However, it is difficult to be bound applying appropriate pressure.

The use of gauze is effective to reduce eye infection, but causes problems like discomfort, ill fitting, and insecurity. The respondents indicate a strong need for developing a new EP at low costs.

Its appearance was generally perceived as neutral (with a mean score of 3.05). Most of the respondents have no comments or special requirements for appearance.

In summary, the mean scores of the sizing system, fitting of the EP_1, security, and safety were lower than 3.00 (<= 3.00) whereas the mean scores of donning/doffing, comfort of fabrics, use of gauze, applicability, and appearance were higher than 3.00 (> 3.00).

3.3.3 Recommendation for EP_n Design

In the survey, further recommendations for EP_n design were collected and are summarized as follows.

(1) Fabrication

- Use of a composite in the eye-patch panel for photo-protection, comfort, sanitary check, and appearance
- Use of elastic materials for holding the eye-patch panel in place effectively and comfortably
- No use of coarse texture materials that may rub against the neonate's soft skin and cause skin irritation

- Use of hook-and-loop fasteners for easy handling and safety

(2) Style design

- Eye-patch panels in a three-dimensional shape for fitting complex face morphology of neonates
- Extending the bottom part of the eye-patch panel to enlarge the effective covering area when the EP is displaced
- Easy to don and doff
- Adjustable fastening panels for fitting various types of head morphology
- Fastening panels covering the occipital region or avoiding it completely

(3) Aesthetical design

- Use of a color design for the aesthetical appearance and the size code

(4) Disposable design

- Inexpensive materials
- Simple design
- Simple manufacturing process

3.4 Criteria for EP_n Design

Based on the qualitative and quantitative results obtained from field observation, focus group interviews, and questionnaire surveys, the basic criteria for the EP development are established as follows:

(1) Photo-protection

It is a critical criterion for the newly developed EP. Photo-protection consists of the following aspects: (a) optimization of the photo-protecting level when the EP is in an optimum position, (b) expansion of the safety region of photo-protection when the EP is displaced, and (c) improvement of the EP's security in the safety region.

(2) Safety

Safety of fabrics consists of flammability and anti-allergy. Any design that may cause strangulation or stabbing of neonates is unacceptable.

(3) Comfort

The physical and sensorial/tactile comforts of materials include high breathability, good handfeel, lightness, and thinness. The comfort of design refers to no bruises, no rubbing, no irritation, and low pressure.

(4) Easy handling

Donning and doffing of the EP should be time-saving and convenient to handle.

(5) Disposability

The criterion aims to keep a good sanitary condition of the EP. Simple, inexpensive textile materials and simple manufacturing procedure are considered.

(6) Appearance

On the basis of functional, comfort, safe, and handling requirements, the aesthetical appearance can increase parents' psychological acceptance of neonatal hospitalization and also the pleasure of the medical staff.

3.5 Specifications of EP_n Design

Design specifications are developed based on six criteria: photo-protection, comfort, easy handling, disposability, safety, and aesthetical appearance. An interaction matrix of design specifications is established (see Table 3-1).

Table 3-1 shows that four pairs of specifications in the matrix, namely (3) “Eye-patch panel should fit facial morphology well” and (14) “Design should be simplified”, (3) “Eye-patch panel should fit facial morphology well” and (15) “Easy to manufacture”, (4) “Fastening panel should hold eye-patch panel in optimum position” and (14) “Design should be simplified”, (4) “Fastening panel should hold eye-patch panel in optimum position” and (15) “Easy to manufacture”, are defined as being in direct conflict with each other. It is because the complex craniofacial morphology and the sleeping posture of the neonate imply that “good-fitting eye-patch panel” and “hold eye-patch panel in optimum position” can result in a complex design and a complex manufacturing process.

Some specifications in the matrix do not conflict directly. Accommodation can be given to a pair of design specifications to lower their conflict. For example, (4) “Fastening panel should hold eye-patch panel in optimum position” and (10) “Design should not cause bruises, rubbing or irritation” hold the EP in an optimum position by a normal type of material that requires tight binding, However, tight binding may cause bruises, rubbing or irritation. Therefore, materials such as elastic band can be applied so as to accommodate the two specifications.

Table 3-1: Interaction matrix of specifications of EP_n design

Criteria	Specifications	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Photo-protection	1. Eye-patch panel should cover eye completely															
	2. Eye-patch panel should provide maximum safety region	O														
	3. Eye-patch panel should fit facial morphology well	O	O													
	4. Fastening panel should hold eye-patch panel in optimum position	O	O	O												
	5. Fastening panel should be adjustable to provide accommodation for all neonates	O	O	O	O											
	6. Size range of EP should cover all neonates	O	O	O	O	O										
	7. Each size should be consistent	O	O	O	O	O	O									
Safety	8. Eye-patch panel should not block nose and cause suffocation	O	O	O	O	O	O	O								
	9. Fastening panel should not cause strangulation, stabbing, etc.	O	O	O	O	O	O	O	O							
	10. Design should not cause bruises, rubbing or irritation	O	O	Δ	Δ	O	O	O	O	O						
Comfort	11. Design should provide low pressure	O	O	Δ	Δ	O	O	O	O	O	O					
Easy handling	12. Fastener should be easy to handle	O	O	O	O	O	O	O	O	O	O	O				
	13. Design of fastening system should be easy to handle	O	O	O	Δ	O	O	O	O	O	O	O	O			
Disposability	14. Design should be simplified	O	O	×	×	Δ	O	O	Δ	Δ	O	O	O	O		
	15. Easy to manufacture	O	O	×	×	Δ	O	O	Δ	Δ	O	O	O	O	O	
Appearance	16. Design should provide aesthetical appearance	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

Remarks: × = Conflict; Δ = Accommodation; O = No conflict

3.6 Conclusions

In this chapter, factors such as the hospital environment, EP wearers in the research (i.e. term neonates), phototherapy units and the assembly, the current EPs, and the practice of care and treatment are examined in the SCBU of QMH. Focus group interviews and questionnaire surveys were conducted to evaluate the current EPs. The problems of the current EPs are identified as security (displacement), fitting of the EP, fitting of the sizing system, and safety. Recommendations on style design and fabrication were collected from the medical staff. The design criteria, including photo-protection, comfort, easy handling, disposability, safety, and appearance, are established. Based on the above-mentioned criteria, the design specifications of the EP and the related interaction matrix are generated. The research results provide practical guidelines for the next stages on the product development process.

CHAPTER 4: DEVELOPMENT OF A MEASURING SYSTEM FOR NEONATAL CRANIOFACIAL MORPHOLOGY AND ANTHROPOMETRIC MEASUREMENT

4.1 Introduction

In Chapter 3, the design criteria and the specifications of EP_n are established based on the exploration of the clinical situation and the problems of current EPs. This chapter and the subsequent chapters describe the 4th stage of the protective product development process— development of a prototype. In this stage, 4 major aspects, including style design, pattern-and-size construction, evaluation of fabric materials, and production are discussed. Of the 4 aspects, style design and pattern-and-size construction are the foundation of clothing development, which influence the photo-protection level of EPs greatly [72, 150]. However, limited research has been done on anthropometric measurement of the neonatal head and/or its applications to textile-based products. The measurement method in particular must be convenient to conduct in neonatal units and must also be safe for neonates. In this chapter, a new anthropometric measuring system approved by the neonatal unit is developed. Anthropometric measurement of neonatal craniofacial morphology was conducted. The results provide accurate measurements and 3D models for pattern construction, development of a sizing system, and development of a neonatal head model. The

scope of the research is shown in Figure 4-1.

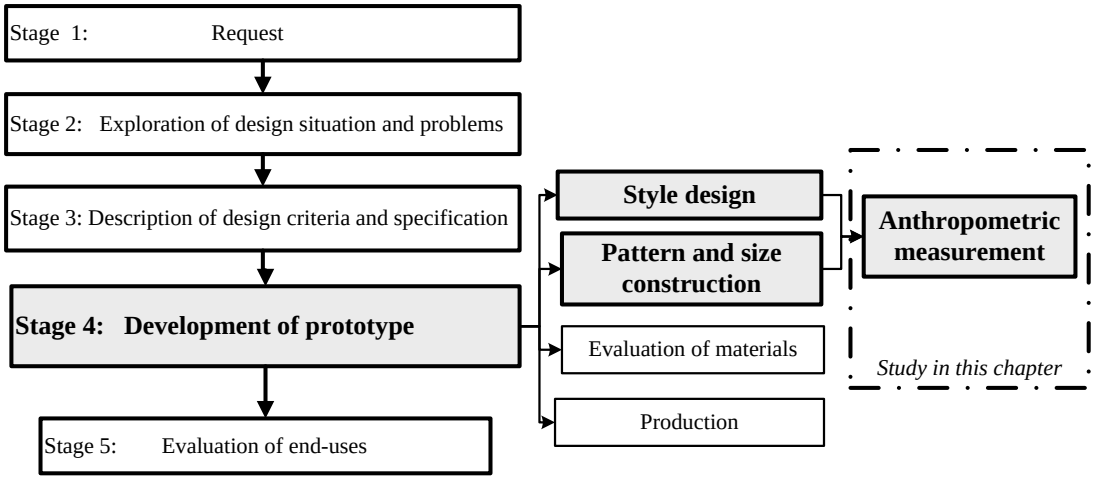


Figure 4-1: Stage 4 of protective product development process

4.2 Measuring Dimensions of Neonates

To design a new EP for neonates in Hong Kong, the characteristics of neonatal craniofacial morphology must be collected and analyzed. Based on Farkas' landmark system [78], a total of 13 landmarks in respect to the development of EPs are identified. Details of the landmark descriptions and locations are presented in Table 4-1.

The morphology of eyes and noses affects the shape of the eye-patch panel of the EP while that of heads and ears affects the shape of the fastening panel. In this research, 16 dimensions which describe the characteristics of eyes, noses, ears, and heads were extracted based on the 13 landmarks introduced by Farkas. The definitions of these dimensions are presented in Table 4-2.

Table 4-1: Landmarks on craniofacial morphology for EP_n development

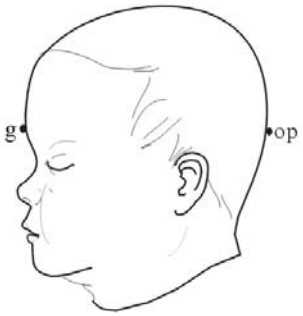
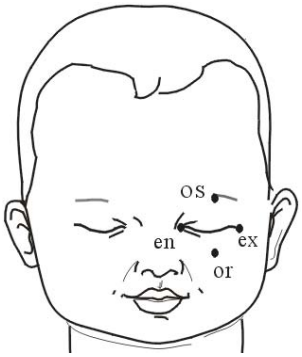
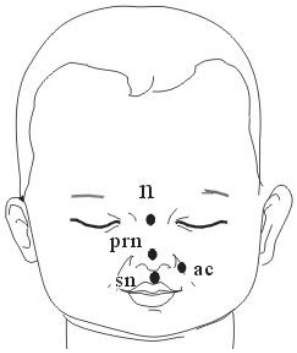
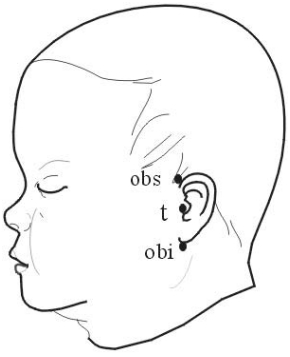
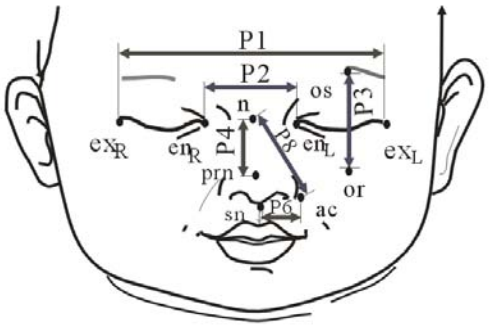
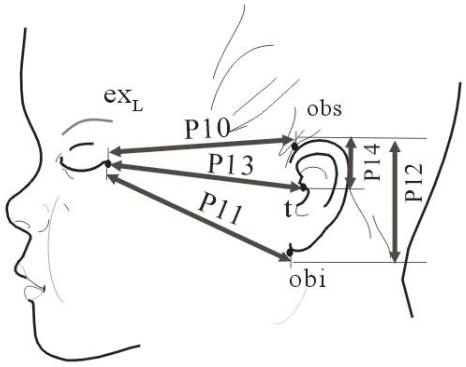
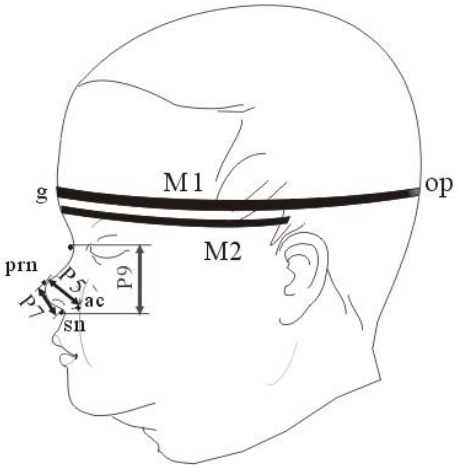
Landmarks	Descriptions	Locations
Glabella (g)	Glabella is the most prominent midline point between the eyebrows and is identical to the bony glabella on the frontal bone.	
Opisthocranion (op)	Opisthocranion is the point situated in the occipital region of the head and is the most distant point from the glabella.	
Exocanthion (ex)	Exocanthion is the point at the outer commissure of the eye fissure.	
Endocanthion (en)	Endocanthion is the point at the inner commissure of the eye fissure.	
Orbitale superius (os)	Orbitale superius is the highest point on the lower border of the eyebrow.	
Orbitale (or)	Orbitale is the lowest point on the lower margin of each orbit.	
Nasion (n)	Nasion is the point in the midline of both the nasal root and the nasofrontal suture.	
Pronasale (prn)	Pronasale is the most protruding point of the apex nasi, identified in a lateral view of the rest position of the head.	
Subnasale (sn)	Subnasale is the midpoint of an angle at the columella base where the lower border of the nasal septum and the surface of the upper lip meet.	
Alar curvature point (ac)	Alar curvature point is the most lateral point in the curved base line of each ala, indicating the facial insertion of the nasal wingbase.	
Otobasion superius (obs)	Otobasion superius is the point of attachment of the helix in the temporal region.	
Tragion (t)	Tragion is the notch on the upper margin of the tragus.	
Otobasion inferius (obi)	Otobasion inferius is the point of attachment of the ear lobe to the cheek.	

Table 4-2: Dimensions of craniofacial morphology for EP_n development

Codes	Dimensions	Illustrations
P1	Binocular width (ex_L-ex_R)	
P2	Intercanthal width (en_L-en_R)	
P3	Height of orbits (os-or)	
P4	Bridge length (n-prn)	
P5	Length of ala (prn-ac)	
P6	Distance from subnasale to alar curvature point (sn-ac)	
P7	Nasal tip protrusion (sn-prn)	
P8	Distance from nasion to alar curvature point (n-ac)	
P9	Nose height (n-sn)	
P10	Distance from exocanthion to otobasion superius (ex-obs)	
P11	Distance from exocanthion to otobasion inferius (ex-obi)	
P12	Width of ear insertion to head (obs-obi)	
P13	Distance from otobasion superius to tragion (obs-t)	
P14	Distance from exocanthion to tragion (ex-t)	
M1	Head circumference	
M2	Facial arc (obs_L-g-obs_R)	

Apart from the above dimensions, basic information about neonates was collected from the hospital (see Table 4-3).

Table 4-3: Basic information on neonates

Codes	Information items	Unit
B1	Gestation	weeks
B2	Age	days
B3	Gender	Male = 1; Female = 2
B4	Present weight	g
B5	Present body length	mm

4.3 Anthropometric Measuring System for Neonates

There are many kinds of anthropometric measuring systems used for fashion product development. However, selection of an appropriate anthropometric measuring system is governed by specific clinical requirements. In view of this, a focus group interview was conducted to identify a suitable measuring system and method for this research.

4.3.1 Requirements of the Anthropometric Measuring System

In this study, 2 pediatric doctors and 8 nurses were invited to join the focus group interview. The routine measuring methods for neonates and the characteristics of neonatal measurement in the neonatal unit were surveyed. The information on the existing anthropometric measuring system for human body measurement based on literature reviews (see Section 2.4.1 of Chapter 2) and field surveys is discussed. The following characteristics of neonatal measurement in the neonatal unit are identified:

(1) Subject: The measured subject is the neonate, who is in the first and most vulnerable period of its life. The instrumentation and operating procedures of the measuring system must be absolutely safe; the subject's cooperation is not required;

and measurements must be taken rapidly to minimize disturbance caused to the neonate.

(2) Measured area: The measured area focused on neonate's craniofacial morphology. The dimension of the eye is so small that it is difficult to measure or even identify. The eye area is the most sensitive area of the human body and therefore the measuring system must be safe, comfortable, and accurate for the small measuring area.

(3) Location: The measurement must be conducted in the SCBU of QMH to guarantee the health and security of the neonates. Medical treatment and care practice should not be interrupted. Referring to the characteristics of the SCBU summarized in Section 3.2.1 of Chapter 3, the measuring system should be portable, small in size, and light in weight. And, most importantly, measurements can still be taken accurately in normal lighting or a relatively dim environment.

(4) Parents' psychological reaction: The neonates nursed in the SCBU are under medical observation, investigation or treatment, but their parents may suffer from shock, emotional disorganization, confusion, rejection or even guilt [28]. In view of this, the operating procedure of the measuring system should be user-friendly and easily accepted by parents.

A summary of the requirements is presented in Figure 4-2.

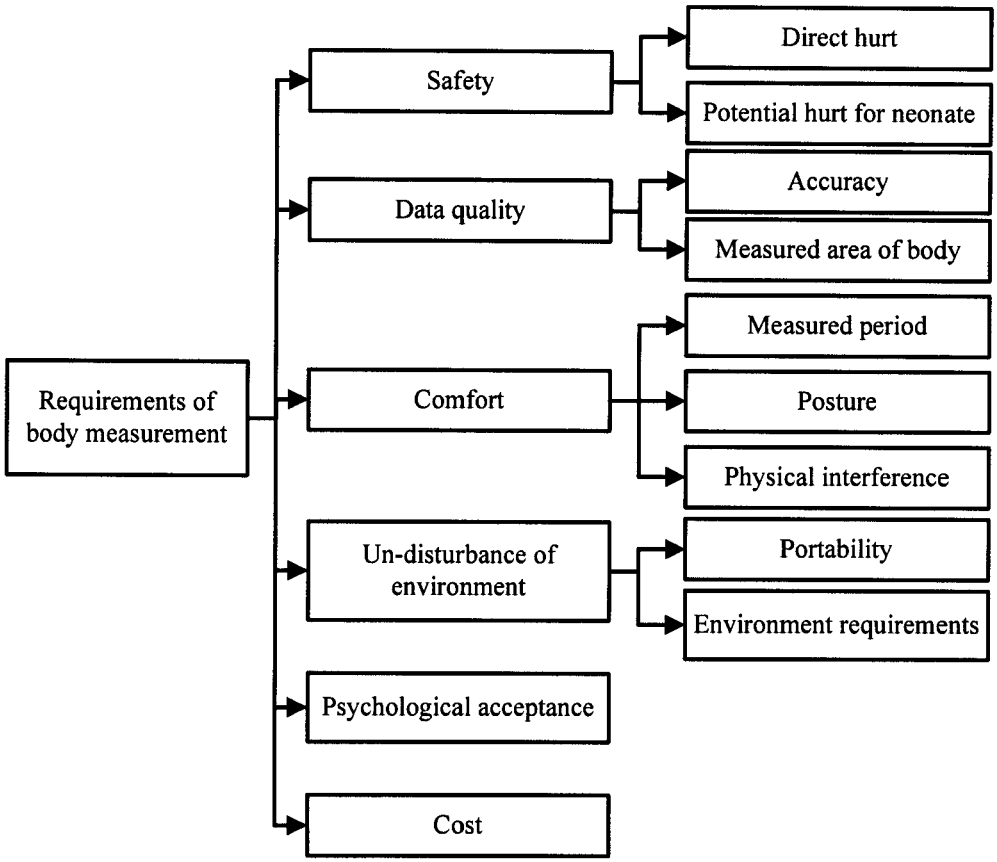


Figure 4-2: Requirements of anthropometric measuring system used in neonatal unit

4.3.2 Selection of the Anthropometric Measuring Method

Based on the requirements for the anthropometric measuring system for neonates used in the neonatal unit, an appropriate measuring method was selected. A summary is presented in Table 4-4. The results indicate that multi-camera convergent close-range photogrammetry can meet all requirements for the anthropometric measurement of neonates in the hospital.

Table 4-4: The identification of anthropometric measuring techniques

Measuring techniques	Requirements for measuring neonatal craniofacial morphology in neonatal units					
	Safety	Data quality	Comfort	Non-disturbance of environment	Psychological acceptance	Cost
Manual measurements	×	×	×	√	√	√
Sliding gauge	×	×	×	×	×	√
Physical moulding	×	√	×	√	×	×
Light sectioning	√	×	×	×	×	√
Moire topography	√	×	×	×	√	√
2D photogrammetry	√	×	×	√	√	√
Stereogrammetry	√	×	×	√	√	√
Multi- camera convergent CRP	**√**	**√**	**√**	**√**	**√**	**√**
Laser scanner	×	√	×	×	×	√
Infrared scanner	×	√	×	×	×	√
CT or MRI	×	√	×	√	√	×

Remarks: √： meet the designated requirement; ×: not meet the designated requirement

4.4 Development of the Multi-camera Convergent CRP System

The convergent close-range photogrammetric system (CRP) is recommended in this research. Since there is no commercial CRP, a CRP-3D measuring system for neonates, including the hardware and software design, was developed in this work.

4.4.1 Principle of CRP System

The fundamental concept applied to CRP is collinearity – a coordinated transformation that describes the relationship between a coordinate measured on a photograph and its corresponding point on the object. The accuracy of the transformation depends upon the location, the orientation of each camera, and the

knowledge of, or ability to model even, the systematic errors of the imaging system, such as lens distortions, the principal distance of the lens, and the location of the principal point. Least squares estimation *(LSE)* provides a systematic method of computing all the components (i.e. object coordinates and systematic imaging errors) based on a large number of redundant measurements of different kinds and weights.

The starting point of building a functional model of CRP is the central perspective projection illustrated in Figure 4-3. Point *A* in the three-dimensional object space is projected onto the projection plane by the straight line *AOa* passing from point *A* through the perspective centre *O*. The perspective axis *Pop* is orthogonal to the projection plane which intersects at *p*, the principal point. The distance *Op* from the perspective centre to the plane of projection is the principal distance, usually denoted as *c*. Points *A* and *a* are homologous points.

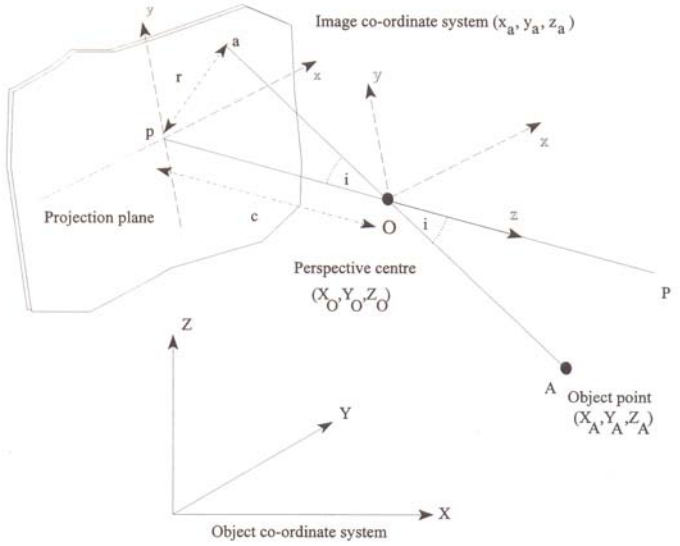


Figure 4-3: The central perspective projection

Two three-dimensional Cartesian co-ordinates systems are now introduced in

order to derive a functional relationship between the position of point *A*, the position of *a*, and the projection of *A*. The primary co-ordinate system *(XYZ)* is located arbitrarily in the object space. In this system, the co-ordinates of the perspective centre of the secondary system are *(Xo,Yo,Zo)* and the co-ordinates of point *A* are (X_A,Y_A,Z_A). The secondary Cartesian system *(xyz)* has its origin at the perspective centre *O*. Its z-axis coincides with the principal axis and is directed away from the plane of projection. Its x- and y-axes are parallel to the plane of projection and are directed so as to complete a right-hand system. The scale factor λ is unity. The coordinates of point *a* in the secondary system are $(x_a,y_a,-c)$. If the written vectors are relative to the primary coordinate system, X_A equals to $X_O + S$ where *S* is the position vector of *A* relative to *O*. X_A is collinear with x_a, but in an opposite sense. Therefore

$$\begin{bmatrix} X_A \\ Y_A \\ Z_A \end{bmatrix} = \begin{bmatrix} X_O \\ Y_O \\ Z_O \end{bmatrix} - \mu \begin{bmatrix} r_{11} & r_{21} & r_{31} \\ r_{12} & r_{22} & r_{32} \\ r_{13} & r_{23} & r_{33} \end{bmatrix} \begin{bmatrix} x_a \\ y_a \\ -c \end{bmatrix} \tag{4-1}$$

where μ is a scalar quantity greater than zero and $\begin{bmatrix} r_{j,11} & r_{j,21} & r_{j,31} \\ r_{j,12} & r_{j,22} & r_{j,32} \\ r_{j,13} & r_{j,23} & r_{j,33} \end{bmatrix}$ are the coefficients for rotation between the image and the object coordinate systems.

Thus, the equation of the transformation can be written as follows:

$$x_a = \frac{-c[r_{11}(Xo - X_A) + r_{12}(Yo - Y_A) + r_{13}(Zo - Z_A)]}{[r_{31}(Xo - X_A) + r_{32}(Yo - Y_A) + r_{33}(Zo - Z_A)]} \tag{4-2}$$

$$y_a = \frac{-c[r_{21}(Xo - X_A) + r_{22}(Yo - Y_A) + r_{23}(Zo - Z_A)]}{[r_{31}(Xo - X_A) + r_{32}(Yo - Y_A) + r_{33}(Zo - Z_A)]} \quad (4\text{-}3)$$

These equations are referred to by photogrammetrists as collinearity equations. They are derived from the collinearity of a point such as *A*, the perspective centre *O*, and the perspective projection of *A* onto the projection plane at *a*.

A multi-station convergent imaging network is illustrated in Figure 4-4. A target point on the object at $A_i(X_i,Y_i,Z_i)$ produces an image point $a_{ij}\,(x_{ij},y_{ij})$ in camera *j*. The coordinate relationship (including the parameters of the systematic errors of the imaging system) between A_i and a_{ij} is given by the self-calibrating form of the collinearity equations:

$$x_{ij} = \frac{-c_j[r_{j,11}(X_{oj} - X_i) + r_{j,12}(Y_{oj} - Y_i) + r_{j,13}(Z_{oj} - Z_i)]}{[r_{j,31}(X_{oj} - X_i) + r_{j,32}(Y_{oj} - Y_i) + r_{j,33}(Z_{oj} - Z_i)]} \quad (4\text{-}4)$$

$$y_{ij} = \frac{-c_j[r_{j,21}(X_{oj} - X_i) + r_{j,22}(Y_{oj} - Y_i) + r_{j,23}(Z_{oj} - Z_i)]}{[r_{j,31}(X_{oj} - X_i) + r_{j,32}(Y_{oj} - Y_i) + r_{j,33}(Z_{oj} - Z_i)]} \quad (4\text{-}5)$$

Considering the parameters of the camera, the collinearity equations become

$$x_{ij} - x_{oj} + (x_{ij} - x_{oj})r_{ij}^{-1}(K_{1j}r_{ij}^3 + K_{2j}r_{ij}^5 + K_{3j}r_{ij}^7) + P_{1j}[r_{ij}^2 + 2(x_{ij} - x_{oj})^2] + 2P_{2j}(x_{ij} - x_{oj})(y_{ij} - y_{oj}) \quad (4\text{-}6)$$
$$+ \frac{c_j[r_{j,11}(X_{oj} - X_i) + r_{j,12}(Y_{oj} - Y_i) + r_{j,13}(Z_{oj} - Z_i)]}{[r_{j,31}(X_{oj} - X_i) + r_{j,32}(Y_{oj} - Y_i) + r_{j,33}(Z_{oj} - Z_i)]} = 0$$

$$y_{ij} - y_{oj} + (y_{ij} - y_{oj})r_{ij}^{-1}(K_{1j}r_{ij}^3 + K_{2j}r_{ij}^5 + K_{3j}r_{ij}^7) + P_{2j}[r_{ij}^2 + 2(y_{ij} - y_{oj})^2] + 2P_{1j}(x_{ij} - x_{oj})(y_{ij} - y_{oj}) \quad (4\text{-}7)$$

$$+ \frac{c_j[r_{j,21}(X_{oj} - X_i) + r_{j,22}(Y_{oj} - Y_i) + r_{j,23}(Z_{oj} - Z_i)]}{[r_{j,31}(X_{oj} - X_i) + r_{j,32}(Y_{oj} - Y_i) + r_{j,33}(Z_{oj} - Z_i)]} = 0$$

where X_{oj} and Y_{oj} are the image coordinates of the principal point, $r_{ij}^2 = (x_{ij} - x_{oj})^2 + (y_{ij} - y_{oj})^2$; (X_{oj}, Y_{oj}, Z_{oj}) are the object coordinates of the perspective center; coefficients K_{1j}, K_{2j} and K_{3j} represent the geometrical effects of radial lens distortion; coefficients P_{1j} and P_{2j} represent the geometrical effects of lens decentring; and c_j is the principle distance [151].

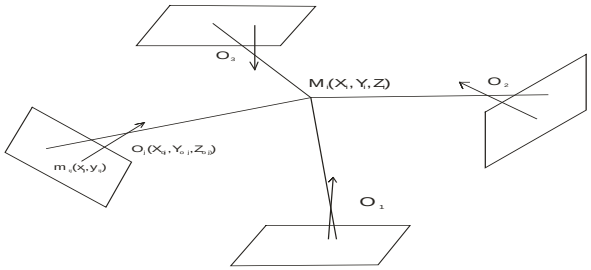


Figure 4-4: Multi-station convergent schematic diagram

4.4.2 Design and Development of the CRP System

4.4.2.1 Hardware and Software Design

The CRP measuring system was developed according to the neonates' unique features and measuring areas, and the measuring conditions of the neonatal units. In this system, web cameras were chosen because several still images can be captured by software simultaneously. More importantly, clear pictures can be obtained in

relatively dark conditions due to their high dynamic range and thus light flashing can be avoided in the hospital environment. A typical 640×480 pixel web camera can provide point coordinate precision values of about 0.1 mm with a level of accuracy good enough for the development of an EP in this project. Its weight is light and its volume is small so that the measuring system is portable and its cost is low.

In view of the geometry design, as the EP is assumed to be symmetrical, the measuring region of the CRP system can focus on two-thirds of the whole neonatal head and face area, including the areas of eyes, nose and right ear. The locations of the web cameras therefore should enable all critical landmarks to be recognized in at least three photographs [152]. As shown in Figure 4-5, the design of the geometry should conform to the following criteria:

(1) Four web cameras are used in the CRP system.

(2) The distance between the subject and each camera is 300 mm.

(3) The axes of the cameras converge at a 40° angle.

(4) Web cameras are fixed to a frame which can be placed around the head of the neonate.

A commercially available software programme, PhotoModeler Version 5.2, was used in this research. PhotoModeler is a window program that can extract measurements and 3D models from photographs. When several photographs of an object are taken and displayed on the screen, the software combines the data and locates the marked features at the three-dimensional bases. The marks become accurately measured points, lines, curves, cylinders or surfaces in a single, unified 3D

space.

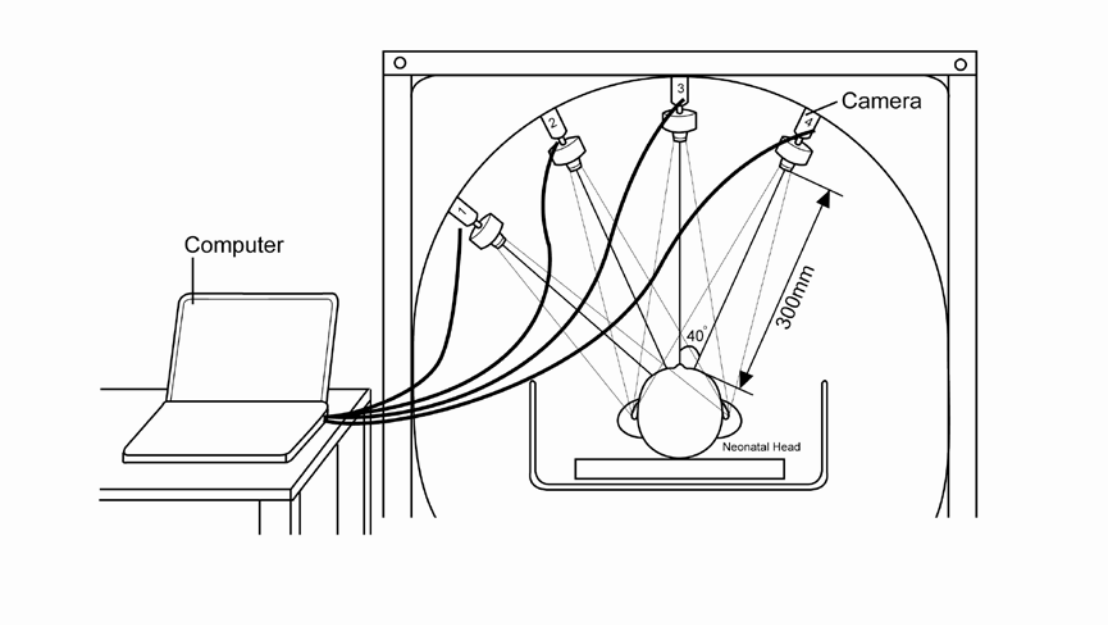


Figure 4-5: The network design of the web-cam CRP system

When the photogrammetric technique is applied to the measurement of moving objects, it is important that the images related to a single measurement epoch are obtained (as closely as possible) simultaneously. Therefore, an image capture programme was developed by Visual Basic 6.0 to capture photographs of a subject simultaneously. Visual Basic is the latest generation of BASIC, which is designed to develop user-friendly programmes easily under the Microsoft Windows operating system.

4.4.2.2 Calibration and Parameters Establishment for the CRP System

In the CRP system, a description of the camera is established to calculate the measurements by PhotoModeler. The description includes focal length, format size,

principal point, lens distortion, and image size. PhotoModeler uses the information to build a proper geometrical relationship between points on the photograph and points in the 3D space. The camera descriptions can be approximate or fully calibrated. Establishment of an approximate camera requires entering information about the camera and creating a camera file. And establishment of a calibrated camera involves taking photos of a calibration pattern and running the camera calibration. Camera calibration is the process of determining the description of a camera accurately. Once a camera is calibrated, it can provide accurate measurements.

To determine the description of a camera accurately, calibration of each web camera was conducted. A set of 8 grid photographs was taken by each web camera and the camera calibration programme was run by PhotoModeler (see Figure 4-6).

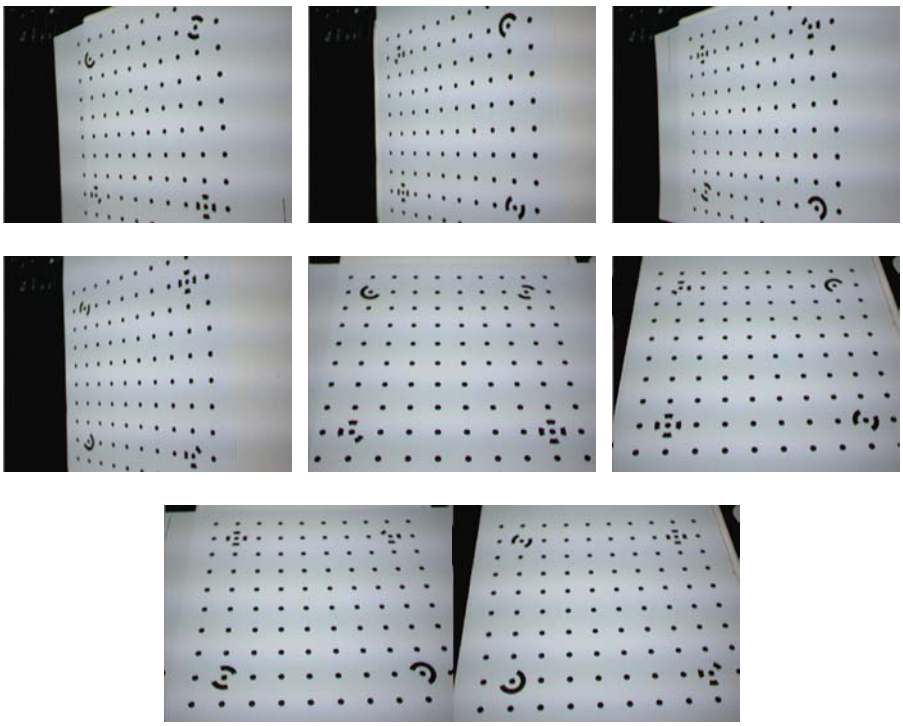


Figure 4-6: A set of photographs for calibration using one web camera

Camera Information Dialog displays the parameters of a camera. In this dialog, Focal Length is the length of the calibrated camera lens, Format Size is the size of the imaging area, and Principal Point is the point where the optical axis of the lens intersects the photograph. Principal Point is a reference point in an image to which all marks and lens distortion parameters are related. In a CCD camera, the principal point is relative to the upper-left corner of the image. Lens Distortion is a set of parameters that describe the two non-linear functions in the radial and the decentering of lens distortion. The parameters of the cameras are shown in Table 4-5.

Table 4-5: The parameters of four web cameras

Parameters		Web Cameras			
		1	2	3	4
Focal Length (mm)		8.4061	8.4832	8.3727	8.4540
Format Size (mm)	W	5.9867	6.0099	6.0161	6.0091
	H	4.5000	4.5000	4.5000	4.5000
Principal Point (mm)	X	2.8146	2.9500	2.7099	2.6810
	Y	2.4868	2.3537	2.3953	2.3453
Lens Distortion	K1	-4.667e-004	2.100e-004	2.801e-004	-1.776e-004
	K2	-1.899e-005	0.000e+000	-5.383e-005	0.000e+000
	K3	0.000e+000	0.000e+000	0.000e+000	0.000e+000
	P1	0.000e+000	0.000e+000	0.000e+000	8.267e-004
	P2	0.000e+000	0.000e+000	0.000e+000	0.000e+000
Image Size (pixel)		640 × 480	640 × 480	640 × 480	640 × 480

Since there are four web cameras used in the CRP system, the parameters of the CRP system are created based on the parameters of the four web cameras. There are two methods of creating parameters of the CRP system: (a) taking the average of the four sets of web cameras parameters, and (b) inputting each set of camera parameters to deal with the corresponding photographs.

To determine the most appropriate parameters of the CRP system, a confirmation process was carried out. The results obtained by the CRP systems with the two above-mentioned methods of creating parameters were compared with the control results obtained by the Steinbichler Comet optical scanner. The design of the Steinbichler Comet optical scanner is based on many years of experience and expertise in optical coordinate measurement, and also a continuous, customer-oriented development. Established as a leading digitizing and scanning system, it is widely used all over the world with its excellent data accuracy (± 0.04~ 0.07 mm) [153].

In the confirmation process, the test subject was a life-size baby dummy. Four photographs of the real-size dummy were taken by the CRP system. To confirm the parameters of the CRP system, three dimensions of the neonatal dummy's head, namely P1, P3 and P7, which run parallel to the three axis of co-ordinates, were measured (see Figure 4-7).

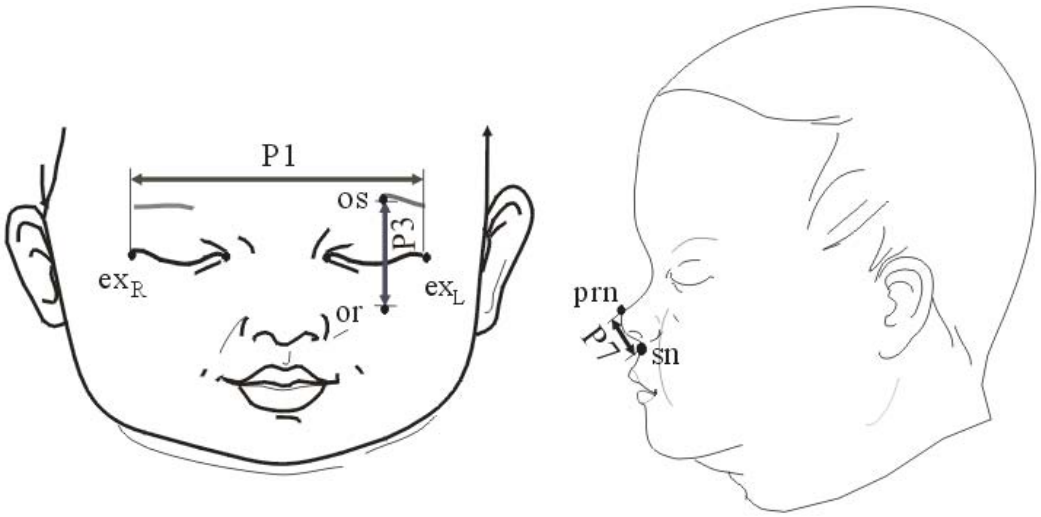


Figure 4-7: Measured dimensions of neonatal dummy in the parameter confirmation process of the CRP system

The dimensions A_1A_2 are calculated according to:

$$A_1A_2 = \sqrt{(x_1 - x_2)^2 + (y_1 - y_2)^2 + (z_1 - z_2)^2} \quad (4\text{-}8)$$

In the confirmation process, three sets of dimensions results were obtained as follows:

Result 1: dimensions obtained by the CRP system with the parameters of the "mean values" of the four web cameras' characteristics

Result 2: dimensions obtained by the CRP system with the parameters of the four cameras

Control Results: dimensions obtained by the Steinbichler Comet optical scanner

Table 4-6: The dimensions obtained by three methods

Results (mm)	P1	P3	P7
Results 1	63.14	24.61	8.18
Results 2	63.03	24.58	8.18
Control Results	63.6	24.6	8.27
Errors (Control results-results 1)	0.46	-0.01	0.09
Errors (Control results-results 2)	0.57	0.02	0.09

The results obtained by the three kinds of measuring systems and the calculated errors are presented in Table 4-6. It shows that the errors of dimensions obtained between control results and results 1 are relatively smaller than those between control results and results 2. As a result, the "mean values" of the four web cameras' characteristics are confirmed as parameters of the CRP system. The mean values of the cameras' characteristics are presented in Table 4-7.

Table 4-7: The parameters of the CRP system

Focal Length (mm)		8.4293
Format Size (mm)	W	6.0055
	H	4.5000
Principal Point (mm)	X	2.7889
	Y	2.3953
Lens Distortion	K1	-3.855e-005
	K2	-3.641e-005
	K3	0.000e+000
	P1	2.067e-004
	P2	0.000e+000
Image Size		640 × 480

4.4.2.3 Construction of the 3D Model Using the CRP System

In this research, the functions of the CRP system are measurement of images and reconstruction of a 3D model. The flowchart of measurement and reconstruction of the 3D model is shown in Figure 4-8. In this process, calibrated cameras should be created firstly. The geometry of cameras was designed to make sure that each feature or target appears on two or more photos. Then photographs were shot simultaneously and imported into PhotoModeler. Features or targets were marked on the photographs and identical features or targets were identified. By starting data-processing, coordinates of features or targets can be obtained and measurement carried out. As a result, a 3D model can be created based on the features and targets for the measurement of the 3D model. It is noteworthy that projection targets are normally used for most of the photogrammetry measurements which aim to improve the texture of the face's surface, resulting in a more accurate identification of landmarks. 3D surfaces can be created based on plenty of landmarks. However, in the CRP system,

projecting patterns onto the neonate's face is not recommended since the high-intensity projection light may cause damage to the neonate's retinas. Therefore, landmarks on the neonate's face are used and the linear segment lengths are measured in the research.

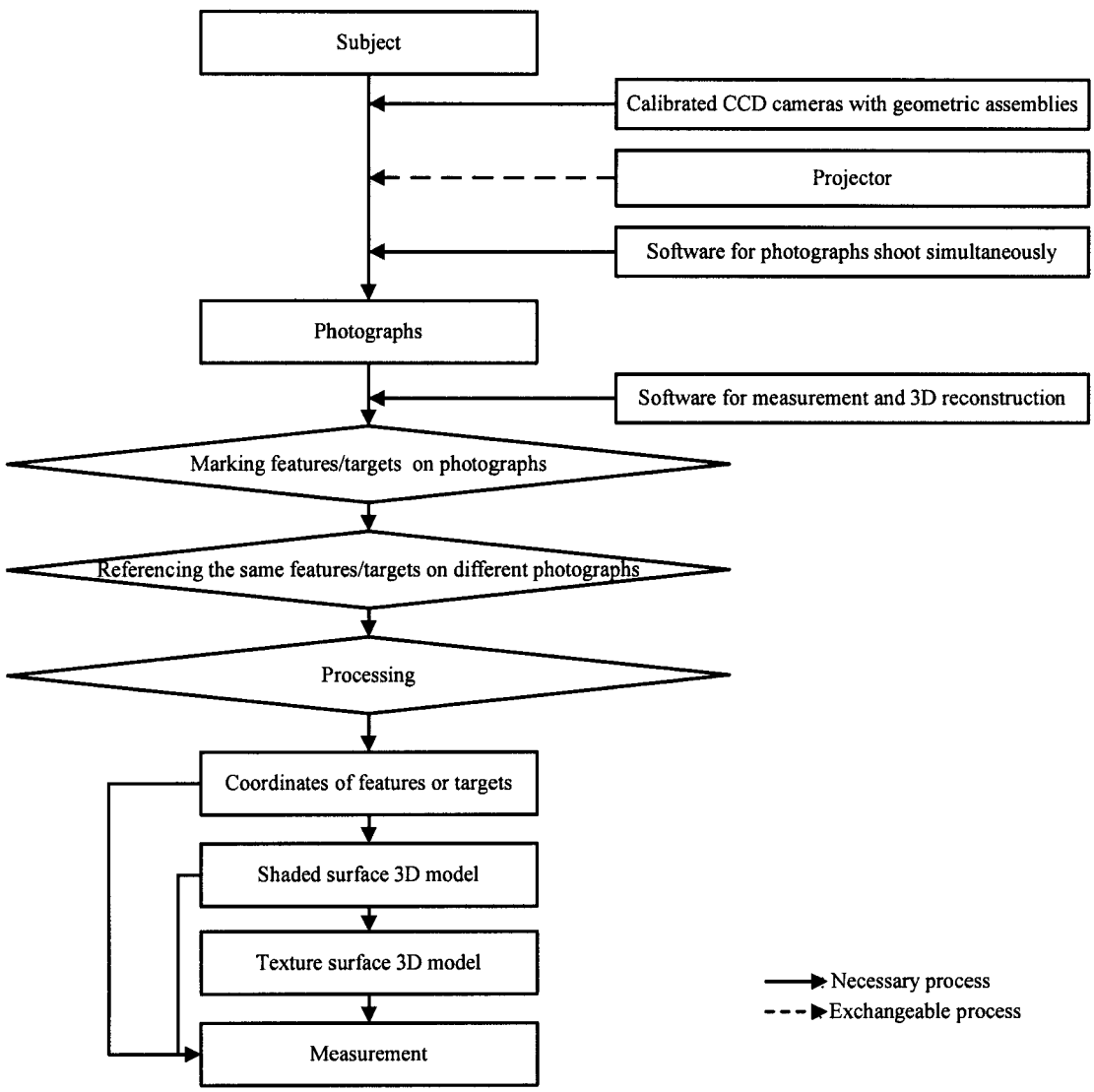


Figure 4-8: Flowchart of 3D reconstruction and measurement

4.4.3 Validation of the Developed CRP System

To validate the accuracy of the developed CRP system, the measurements obtained by the CRP system were compared with the results measured by the Steinbichler Comet optical scanner, the accuracy of which was ± 0.04~ 0.07 mm. A life-size neonate dummy was measured by both systems. A total of seven segment dimensions, namely P1, P2, P3, P4, P5, P7, and P12, were designated as key measuring items in anthropometric measurement determined by the CRP system and the optical scanner (see Figure 4-9).

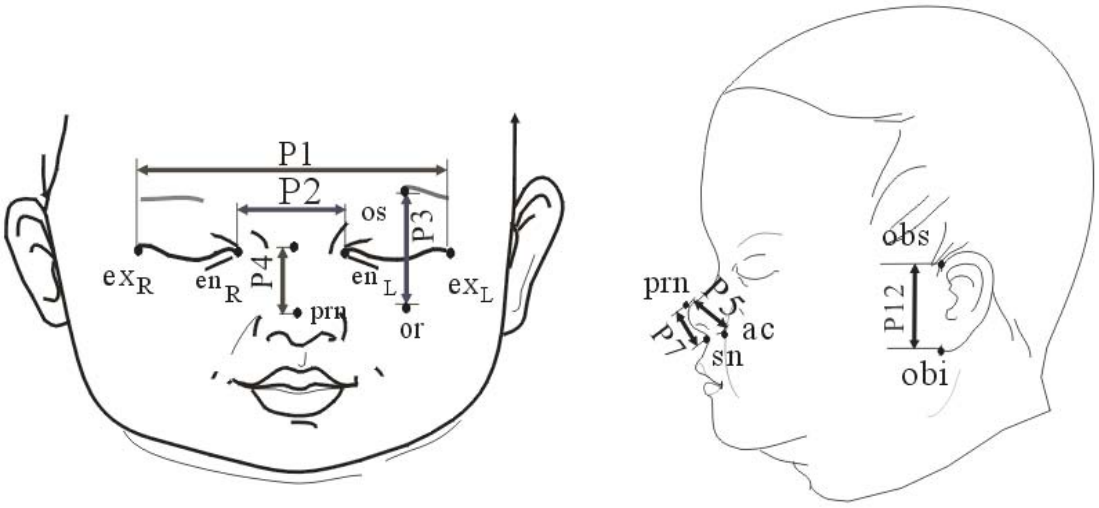


Figure 4-9: The measured dimensions in validation of the CRP system

The errors of the measured dimensions between the two measuring systems are presented in Figure 4-10. According to the results, the smallest value was 0.01 mm at P3 while the largest one was 0.46 mm at P1. Potential sources of error could be found at the geometry of cameras in the system, the number of photographs, the calibration of cameras, and the detection of the landmarks.

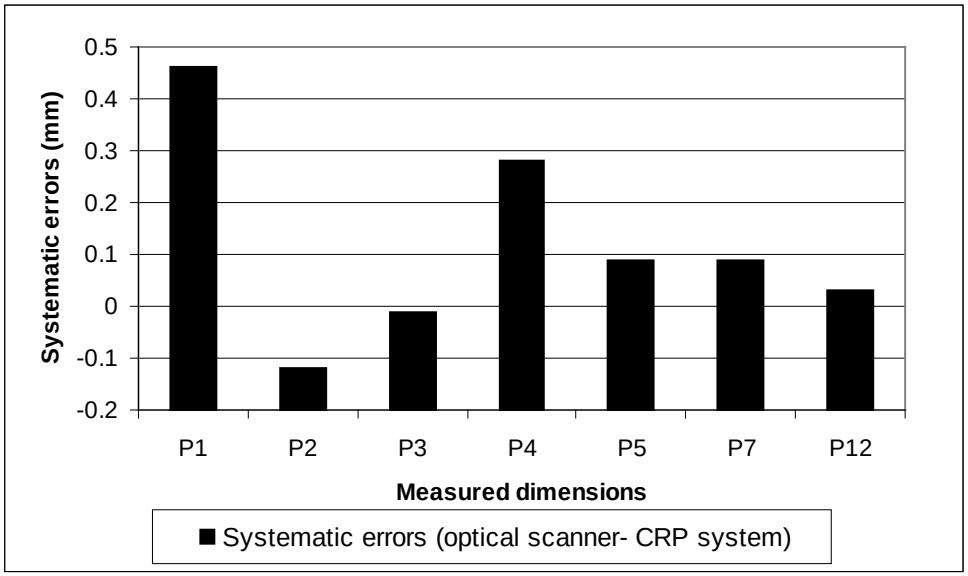


Figure 4-10: Systematic errors of dimensions from the optical system and the CRP system

In this study, the random error of the results was also determined as it affects the precision of the CRP system. In the output of the PhotoModeler software, point precision refers to the expected spread of its estimated value. Precision values of the seven segment dimensions measured by the CRP system can be calculated based on point precision according to the application of the special law of variance propagation to the equation of the distance between two 3D points.

$$\sigma_f = \left(\frac{\Delta X^2(\sigma_{X_1}^2 + \sigma_{X_2}^2) + \Delta Y^2(\sigma_{Y_1}^2 + \sigma_{Y_2}^2) + \Delta Z^2(\sigma_{Z_1}^2 + \sigma_{Z_2}^2)}{(X_2 - X_1)^2 + (Y_2 - Y_1)^2 + (Z_2 - Z_1)^2} \right)^{1/2} \quad (4\text{-}9)$$

The results of dimension precision values are presented in Figure 4-11.

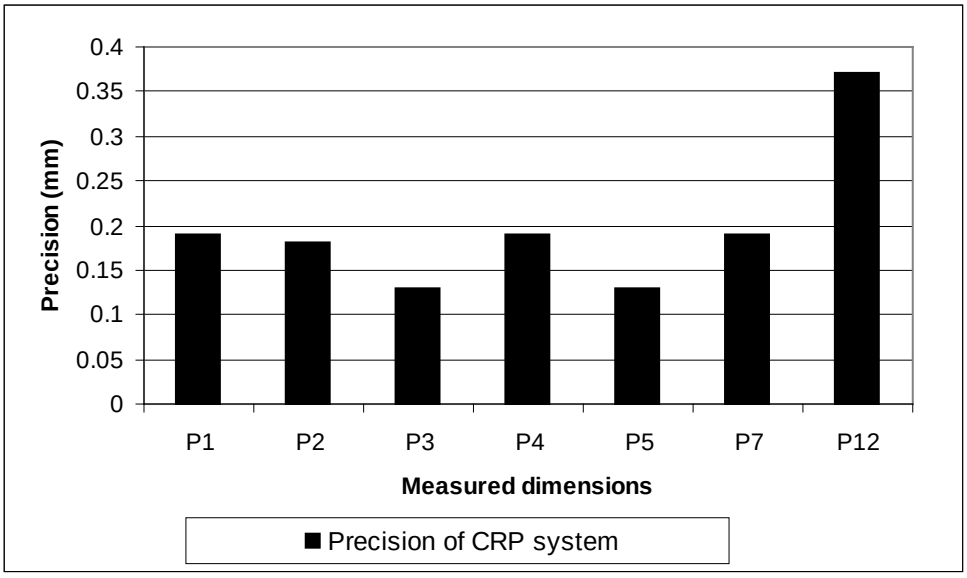


Figure 4-11: Precision values of dimensions measured by CRP system

The largest precision value of 0.37 mm was obtained at P12 and the smallest precision value of 0.13 mm was found at P3 and P5. The results were further tested for significance at a 95% confident interval (see Table 4-8).

Table 4-8: Value of segment dimensions

Measured dimensions	Value ± 2 precision (mm)
P1	63.14 ± 0.38
P2	23.22 ± 0.36
P3	24.61 ± 0.26
P4	14.22 ± 0.38
P5	14.31 ± 0.26
P7	8.18 ± 0.38
P12	33.77 ± 0.74

As shown above, the systematic errors of the seven dimensions were less than 0.5 mm and the precision values of the seven segment dimensions were less than 0.5 mm. The requirements for measurement accuracy should be established on the basis of the application. For developing an EP, the design and fitting of EP cannot be

affected by a 1 mm error and the cutting and sewing tolerances of an apparel product are normally larger than 1 mm. Therefore, the consistency and accuracy of the CRP system are good enough for the development of an EP in this research.

While the system has a distinct value as a measuring tool because it offers a safe, comfortable, and convenient means of recording information on neonates, the validation results of the system show that the accuracy and precision of the CRP system meet the requirements for measuring quality which is established on the basis of the application. Thus, the CRP system is an appropriate measuring tool applied to this research.

4.5 Anthropometric Measurement and Analysis

By using the web camera-based CRP system, the anthropometric measurements of neonates were conducted in the SCBU of QMH.

4.5.1 Anthropometric Measurement of Neonate in Hospital

The anthropometric measurements of neonates were carried out with the aims of pattern construction and sizing-system development for a new EP. All full-term neonates nursed in the SCBU of QMH were eligible to participate in the study. A total of 41 full-term neonates in QMH participated in anthropometric measurements for 4 months. All subjects' parents were informed of the purpose of the study before signing a patient consent form which had been reviewed and approved by the Institutional

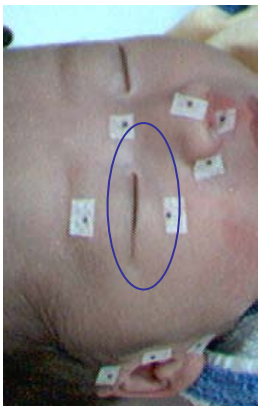
Review Board of The University of Hong Kong of Hospital Authority Hong Kong West Cluster.

In this measurement, the basic information on neonates, including gestation (B1), age (B2), and gender (B3), was gathered from the neonatal clinical records. The weights of the neonates (B4) were taken by the medical electronic digital weight balance, Detecto. The body length (B5), head circumference (M1), and facial arc (M2) were measured by a 920 mm disposable paper tape, marked in centimeters and millimeters. The balance and the tape are used in the SCBU of QMH routinely. Other segment dimensions (P1-P14) were taken by a self-developed webcam-based multi-camera convergent CRP system. Measuring space was managed in the SCBU of QMH while measurement was conducted by an experienced medical staff member.

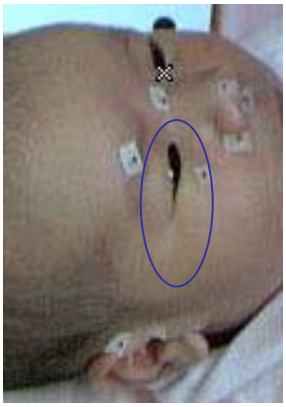
For taking the measurements of craniofacial dimensions, landmark marking is necessary and important; otherwise it will be difficult to identify points from the smooth faces of neonates, especially when those landmarks on the bony points are covered by soft tissues. The landmarks must be recognized by the photogrammetric system and thus the same points obtained from different photographs can match. When a point is marked in one photograph, the same point in the other photographs should also be marked. The synchronization of the point is used to decide its coordinate. Because the subjects are neonates, it is of critical importance to define carefully what landmarks are to be labeled considering the balance between measurement requirements and safety requirements.

Among the landmarks, exocanthion (ex) and endocanthion (en) are the most

unfeasible to mark because (1) the neonates' eyes are closed most of the day, (2) blinking makes it difficult to fix markers to the landmarks, and (3) the marking probably causes discomfort to the neonates or even hurts their eyes. According to clinical investigation, the photographed features of the unmarked neonatal exocanthion and endocanthion in both opening and closing situations are as discernible as the marked landmarks obtained in photographs. In addition, the operator has enough time to identify the landmarks on the photographs accurately after the clinical experiment. Therefore, that exocanthion and endocanthion are defined as unmarked landmarks guarantees the safety of measurement of neonates. In this research, non-marked landmarks were determined as ex_R, ex_L, en_R, and en_L, while marked landmarks as os, or, n, sn, prn, ac, obs, obi, and t. Considering the strict safety requirements, the markers were made of medical adhesive tape with small printed black dots and the skin of the neonates was carefully marked by experienced medical staff. When taking photographs, the neonate's head was carefully controlled in an appropriate position.



(a) *ex* and *en* when neonatal eyes are closed



(b) *ex* and *en* when neonatal eyes are open

Figure 4-12: Identification of landmarks *ex* and *en* in photos

4.5.2 Measuring Results and Preliminary Analysis

The full-term neonates, 25 male and 16 female, nursed in the SCBU of QMH in Hong Kong were selected for the study. The basic individual information and anthropometric data about the neonates are given in Appendix 1. The preliminary analysis of the basic information on the neonates, including range, minimum, maximum, mean ($\bar{x}$), standard deviation (s), and coefficient of variation (cv), was carried out and the results are presented in Table 4-9.

Table 4-9: Preliminary analysis of basic information on neonates

Basic Information	Range	Minimum	Maximum	$\bar{x}$	s	cv
B1 (week)	4.6	37.1	41.7	39.5	1.3	35.5
B2 (day)	10.0	0.0	10.0	3.4	2.9	85.3
B4 (g)	230.0	2265.0	4495.0	3214.6	482.0	15.0
B5 (mm)	160.0	440.0	560.0	500.0	23.9	4.8

The measured craniofacial anthropometric dimensions of the subjects analyzed by univariate and ratio methods. The data processed by the univariate analysis consist of range, minimum, maximum, mean ($\bar{x}$), standard deviation (s), coefficient of variation (cv) and selected percentiles (5th, 50th and 95th) (see Table 4-10).

Table 4-10: Univariate analysis of craniofacial dimensions (unit: mm)

Dimensions	Range	Minimum	Maximum	$\bar{x}$	s	cv	Percentiles		
							5th	50th	95th
M1	62.0	318.0	380.0	346.7	13.3	3.8	320.1	349.0	367.0
M2	86.0	149.0	235.0	171.0	14.3	8.4	150.0	170.0	189.7
P1	35.3	55.1	90.4	68.7	5.9	8.6	56.8	68.7	76.4
P2	8.4	20.7	29.1	24.1	1.9	7.9	21.0	24.1	27.7
P3	10.4	13.6	24.0	19.5	2.1	10.7	16.0	19.8	23.3
P4	14.9	13.3	28.1	16.0	2.6	16.6	13.6	15.2	21.6
P5	7.1	12.5	19.6	15.7	1.3	8.1	14.0	15.4	17.8
P6	8.7	8.8	17.5	12.6	1.4	11.4	10.6	12.7	15.4
P7	6.1	8.3	14.4	10.3	1.4	13.5	8.4	10.2	13.8
P8	14.9	20.1	35.0	23.9	2.7	11.5	20.3	23.3	29.1
P9	17.8	19.2	37.0	22.8	3.0	13.1	19.8	22.2	27.7
P10	15.9	36.2	52.1	44.4	4.0	9.1	36.6	44.1	51.9
P11	14.5	40.8	55.3	46.8	3.7	7.9	41.1	47.0	54.5
P12	12.5	18.7	31.2	24.6	2.9	12.0	19.8	24.8	29.5
P13	16.0	35.7	51.7	43.4	3.8	8.8	37.0	43.3	49.9
P14	7.3	7.8	15.1	12.0	1.6	13.5	8.8	11.9	14.8

Ratios and angles of craniofacial dimensions were generated by the univariate analysis (see Table 4-11) and are of utmost importance for the description of the craniofacial features of the neonates.

Table 4-11: The ratios of craniofacial dimensions

Ratios	Results
P1 : P2	2.9 : 1
P1: P3	3.5 : 1
M1: M2	2.0 : 1
P8: P9: P4	1.5 : 1.4 : 1
P5: P6: P7	1.5 : 1.2 : 1
∠obs-ex-obi: ∠t-ex-obi	2.0 : 1

4.5.3 Development of a New Sizing System

Currently, EP_1 used in the hospital comes in three different sizes. The small

premie-size EP_1 is provided for the small premature neonates whose head circumferences range from 200 to 240 mm; the premie-size EP_1 is for the premature neonates whose head circumferences range from 230 to 340 mm, and the newborn-size EP is for the full-term neonates whose head circumferences range from 300 to 350 mm. In this study, the mean (range) head circumference of the full-term neonates is 346.73 mm (318-380 mm) and the apex is located at 350-360 mm. Apparently, there are 46.0% of the full-term neonates whose head circumferences are over 350 mm and exceed the size range of the EP provided for the full-term neonates. Therefore, a new sizing system is in desperate need of an EP to cover all full-term neonates and to provide maximum protection from potential retinal or corneal damage.

4.5.3.1 Identification of Key Dimensions for New Sizing System

To build a sizing system, key body dimensions should be chosen to divide the population of neonates into different size groups. The key body dimensions must satisfy the following criteria [72]:

(1) It is convenient to measure;

(2) The body dimensions should be an integral part of the product;

(3) There is a high degree of correlation with other dimensions crucial to sizing;

(4) They are not highly correlated with each other.

A correlation analysis was carried out to investigate the relationship between the

measurements based on the following equation:

$$r = \frac{\sum (x - \bar{x})(y - \bar{y})}{\sqrt{\sum (x - \bar{x})^2 \sum (y - \bar{y})^2}} \qquad (4\text{-}10)$$

where r is the correlation coefficient, x and y are the individual measurements, and $\bar{x}$ and $\bar{y}$ are the means of the individual measurements for which the correlation coefficient is to be found. The matrix of correlation coefficients (r) is presented in Appendix 2. The analysis shows that there was a strong correlation between the three integral body dimensions, namely B4, B5 and M1 (r_{B4*B5} = 0.823, r_{B4*M1} = 0.827, r_{B5*M1} = 0.756 respectively), which are regularly taken in the hospital to monitor the growth of the neonates. A relatively good correlation also existed between the three integral body dimensions and most of the other dimensions. B4 had a moderately good correlation with P1 (r_{B4*P1} = 0.734), P2 (r_{B4*P2} = 0.613), P10 (r_{B4*P10} = 0.584), P11 (r_{B4*P11} = 0.697), and P13 (r_{B4*P13} = 0.657); B5 showed a mild correlation with M1 (r_{B5*M1} = 0.756), P1 (r_{B5*P1} = 0.555), P2 (r_{B5*P2} = 0.572), P11 (r_{B5*P11} = 0.608), and P13 (r_{B5*P13} = 0.511); and M1 demonstrated a certain degree of correlation with B5 (r_{M1*B5} = 0.756), P1 (r_{M1*P1} = 0.701), P2 (r_{M1*P2} = 0.634), P10 (r_{M1*P10} = 0.600), P11 (r_{M1*P11} = 0.753), and P13 (r_{M1*P13} = 0.636). Strikingly, M1 had a mild correlation with almost all the transverse dimensions. However, the results of correlation coefficients identified no dimension indicating the development of other longitudinal dimensions. Obviously, no significant relationship existed between longitudinal and transverse dimensions. Other findings showed that P3, the critical anthropometric dimension of

developing an EP, had a weak correlation with other dimensions. In addition, among the nose dimensions, any two of the dimensions of P4, P8 and P9 had a strong correlation ($r_{P4*P8} = 0.846$, $r_{P4*P9} = 0.932$, $r_{P8*P9} = 0.864$) with each other. Yet the whole dimensions of the nose area (P4-P9) showed a low correlation with other dimensions. Above results indicates that the development of nose morphology is relatively independent. As for the dimensions of the ear area and the dimensions between eyes and ears, P10, P11 and P13 had a strong correlation between each other ($r_{P10*P11} = 0.770$, $r_{P10*P13} = 0.898$, $r_{P11*P13} = 0.843$). P11 had a mild correlation with P12 ($r_{P11*P12} = 0.529$).

A factor analysis was conducted in order to detect the structure of the relationship between different variables, and to examine factors that explain most of the data variability. Table 4-12 shows that the first six factors account for 77.1% of the total variability in the data set. The outcome further endorses the results obtained from the multiple correlation analysis. The six factors of the craniofacial anthropometric data about neonates are classified as follows:

(1) Factor 1 has a high loading on longitudinal dimensions of the nose;

(2) Factor 2 has a high loading on transverse dimensions of the head and eyes;

(3) Factor 3 has a high loading on transverse dimensions between eyes and ears;

(4) Factor 4 has a high loading on longitudinal dimensions of ears;

(5) Factor 5 has a high loading on transverse and vertical dimensions of nose;

(6) Factor 6 has a high loading on longitudinal dimension of the eye.

Table 4-12: The results of factor analysis

Variable	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
M1		**0.703**				
M2		**0.780**				
P1		**0.661**				
P2		**0.851**				
P3						**0.912**
P4	**0.943**					
P5	**0.585**					
P6					**0.604**	
P7					**0.892**	
P8	**0.908**					
P9	**0.922**					
P10			**0.847**			
P11			**0.691**			
P12				**0.769**		
P13			**0.830**			
P14				**0.792**		

The results clearly present a structure of relationship among different craniofacial dimensions. They show that transverse dimensions and longitudinal dimensions of each eye, ear, and nose are classified into different groups. Each pair of transverse dimensions including head circumference (M1), facial arc (M2), transverse dimensions of eye (P1, P2), and distance between eye and ear (P10, P11 and P13) had strong-to-mild correlations. Each pair of longitudinal dimensions of nose (P4, P8 and P9) had high correlations. The longitudinal dimensions of ear (P12 and P14) had mild correlations. No significant relationships exist between longitude dimensions of eye, ear, and nose. No significant relationships exist between the longitudinal and transverse dimensions. The findings provide a framework for the size chart

development. Among the transverse dimensions, M1, the head circumference, is an integrated dimension of the EP and has a strong or mild correlation with the transverse dimensions of the head, the eyes and those between the eyes and the ears. In addition, the head circumference is routinely measured in the hospital for the medical staff to select EPs of suitable size for the neonates conveniently. Accordingly, M1 was determined as one of the key dimensions of developing a new sizing system. Regarding the longitudinal dimensions, there is no key dimension generated from the longitudinal dimensions of developing a sizing system. Consequently, only M1 is confirmed as the key dimension of developing a new sizing system for the EP.

4.5.3.2 Size Chart for New Sizing System

Among the 41 neonates measured in the research, it was found that the range of head circumference is 318-380 mm. The details are presented in Figure 4-13.

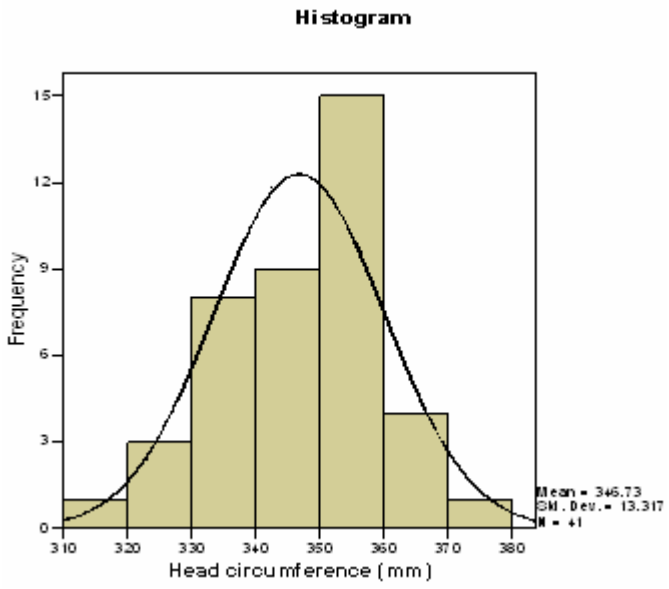


Figure 4-13: Histogram of head circumferences of neonates

As 46.0% of the full-term neonates whose head circumferences were over 350 mm, which is the maximum size in the sizing system of Posey®, one more size was designed to cover the target population of full-term neonates. Since the distribution of head circumference was nearly normal, 99.7% of the measured data were in the range of $\bar{x} \pm 3s$. The range of head circumferences was calculated as 306.7-386.7 mm and divided into two ranges — 310-349 mm and 350-389 mm. The established size chart is presented in Table 4-13 (Given the use in the EP development, the measurement unit is mm with 0 decimal digits).

Table 4-13: Size chart of EP_n for full-term neonates (unit: mm)

Sizes	Small size			Medium size	
Median of size	330			370	
Range of size	310-349			350-389	
Dimensions	$\bar{x}$	5%	95%	$\bar{x}$	5%	95%
P1	65.6		72.2	71.9		89.7
P2	23.4	20.8		25.8	22.8	
P3	19.3		23.2	19.7		23.9
P4	16.0			16.0		
P5	15.6			15.7		
P6	12.6			12.6		
P7	10.2			10.5		
P8	23.5			24.4		
P9	22.4			23.2		
P10	42.4			46.5		
P11	44.2			49.5		
P12	23.1			26.2		
P13	41.3			45.6		
P14	11.3			12.6		
M2	166.2			176.0		

4.5.3.3 The Recommendations for EP Design

The recommendations for EP design were generated as follow:

(1) A rectangular or ellipse shape for EP panel;

(2) The length of EP is governed by head circumference(M1);

(3) Binocular width (P1) < length of EP panel < facial arc (M2);

(4) Height of orbits (P3) < width of EP panel < 2 X nose height (P9);

(5) A concave shape EP panel for nose accommodation, governing by nose dimensions (P4－P9) & width of intercanthal width (P2);

(6) The width of fastening panel at ear location is governed by the width of ear insertion to head (P12);

(7) Design of fastening panel is governed by the distance between eye and ear (P10, P11 and P13);

(8) The top band, if needed, is suggested to be at the ear location for secure binding.

4.6 Conclusions

A web camera-based convergent close-range photogrammetric system was developed to meet the requirements for safety, data quality, comfort, minimum interruption, psychological acceptance, and low cost for neonatal morphologic measurment. Using this measuring system, craniofacial dimensions of 41 full-term neonates were measured and basic information including gestation, age, gender,

present weight and body length was collected. The univariate analysis processed data, including range, minimum, maximum, mean, standard deviation, coefficient of variation, and selected percentiles of the calculated craniofacial dimensions. According to the correlation analysis and the factor analysis, the head circumference was confirmed as a key dimension of a new sizing system. Two sizes (i.e. small size and large size) were designed in the sizing system of the new EP according to the distribution of the neonate's head circufmerence while the measured full-term neonates was divided into two groups. The size chart was established based on the dimensions of these two population groups. And recommendations for EP design were generated.

CHAPTER 5: DEVELOPMENT OF AN EP FOR THE FIRST WEAR TRIAL

5.1 Introduction

Based on the design criteria/specifications and the quantitative craniofacial characteristics of neonates, this chapter presents Stage 4 of the protective product development process (i.e. the development of prototype). It includes fabrication and evaluation of fabric materials, style design, pattern construction, and production of the EP prototype (see Figure 5-1). A prototype of EP_n is thus developed, and its end-use will be evaluated in the next stage.

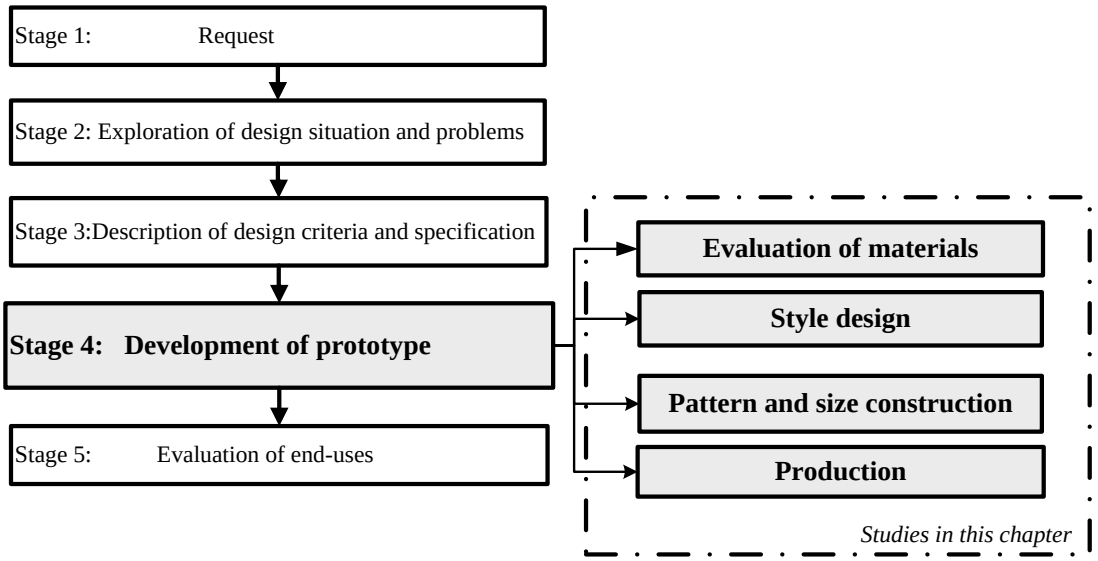


Figure 5-1: The stage 4 of protective product development process

5.2 Fabrication and Materials Evaluation of EP_n

According to the literature review, the focus group interview, and the questionnaire survey, the fabric's physical and physiological requirements for development of an EP were identified. The fabrication requirements for the eye-patch panel are different from those for the fastening system in terms of comfort, photo-protection performance, control of displacement, etc. Details are discussed below.

5.2.1 Fabrication of Eye-patch Panel of EP_n

5.2.1.1 Light Transmittance of Fabric Materials

The prime function of an EP is to protect the neonate's eyes from retinal damage caused by phototherapy treatment of neonatal jaundice. Blue light in the wavelength range of 400-500 nm, and white light in the wavelength range of 350-800 nm, both of which are in the visible light range, are usually used in phototherapy treatment. Keybus *et. al.* studied the level of protection given by textile materials from visible light on human skin [58]. The results reveal that almost all structural indices of textile materials, especially fabric color, weight, and structure, have a direct impact on the transmittance of visible radiation and the light protection of fabric.

In this research, a pilot study of light transmittance affected by fabric construction and color was conducted. The light transmittance results of two series of fabric samples were measured by a Cary UV/Visible spectrophotometer using the

AATCC 183-2004 method. The specifications of the fabrics are presented in Table 5-1.

Table 5-1: The specifications of tested fabrics

Series		Content	Color	Construction	Weight (g/m^2)	Thickness (mm)	Yarn count		Fabric set	
							Warp (tex)	Weft (tex)	Ends(or wale)/cm	Picks(or course)/cm
I	A	100% cotton	White	Knitted	100.8	0.54	14.5		15.9	17.8
	B	95% cotton/ 5% spandex	White	Knitted	207.6	0.81	14.5		18.2	27.2
	C	95% cotton/ 5% spandex	White	Knitted	258	1.19	18.0		15.9	24.4
	D	96% cotton/ 4% spandex	White	Woven (1/2 twill)	240.8	0.50	36.9	36.9	44.4	15.7
II	E	96% cotton/ 4% spandex	White	Woven (1/2 twill)	240.8	0.50	36.9	36.9	44.4	15.7
	F	96% cotton/ 4% spandex	Yellow	Woven (1/2 twill)	240.8	0.50	36.9	36.9	44.4	15.7
	G	96% cotton/ 4% spandex	Green	Woven (1/2 twill)	240.8	0.50	36.9	36.9	44.4	15.7
	H	96% cotton/ 4% spandex	Blue	Woven (1/2 twill)	240.8	0.50	36.9	36.9	44.4	15.7
	I	96% cotton/ 4% spandex	Red	Woven (1/2 twill)	240.8	0.50	36.9	36.9	44.4	15.7
	J	96% cotton/ 4% spandex	Black	Woven (1/2 twill)	240.8	0.50	36.9	36.9	44.4	15.7

Figure 5-2 presents the light transmittance results obtained from the 4 studied fabrics (Series I) at the wavelength range of 350-800 nm. Among the 3 knitted fabrics (A, B and C), the results indicated that fabric weight and thickness had a significant impact on the value of light transmittance. That is, heavy fabrics had lower values of light transmittance. Fabric D (twill woven structure) also gave low values of light transmittance, even though its thickness is only half of Fabric C. It is also noteworthy that the light transmittance of knitted fabrics increased steadily when fabrics were

extended.

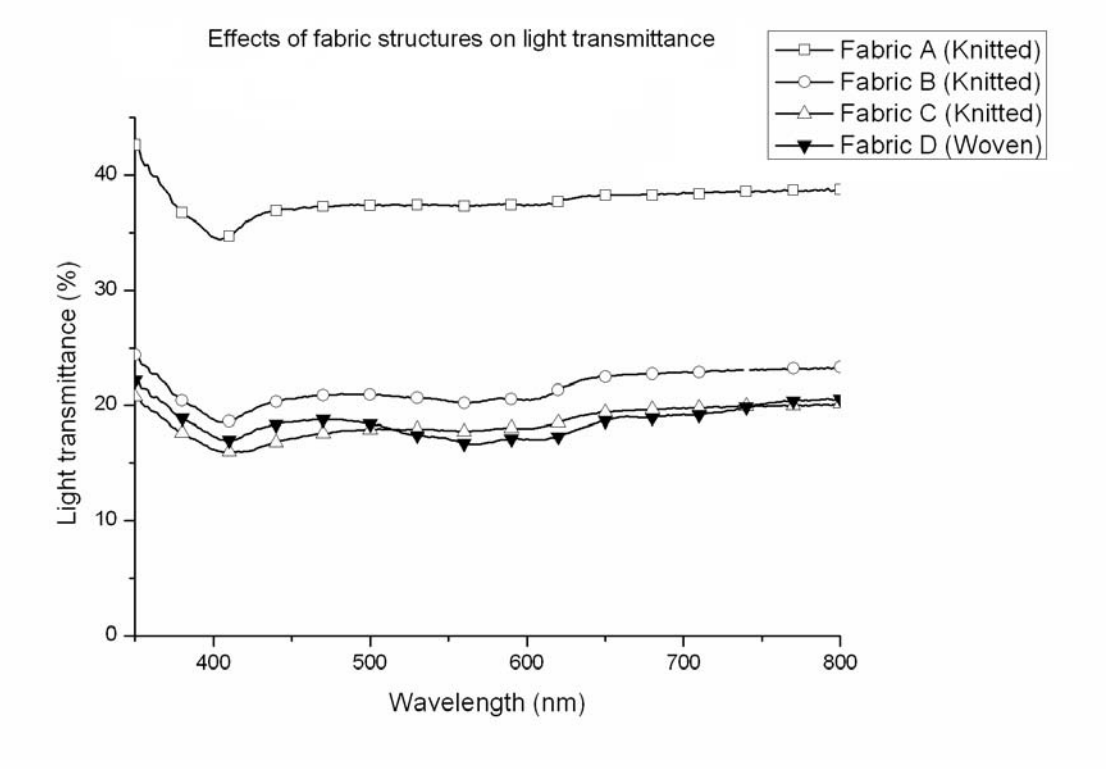


Figure 5-2: Light transmittance of the 4 studied fabrics

Figure 5-3 shows that fabrics of different colors had a major effect on light transmittance at the wavelength range of 350-800 nm. A total of 6 fabrics of the same structure but different colors were measured. The results reveal that white fabrics had the highest values of light transmittance, while black fabrics had the lowest values of light transmittance. The mean value of light transmittance for black fabrics was only 0.008%.

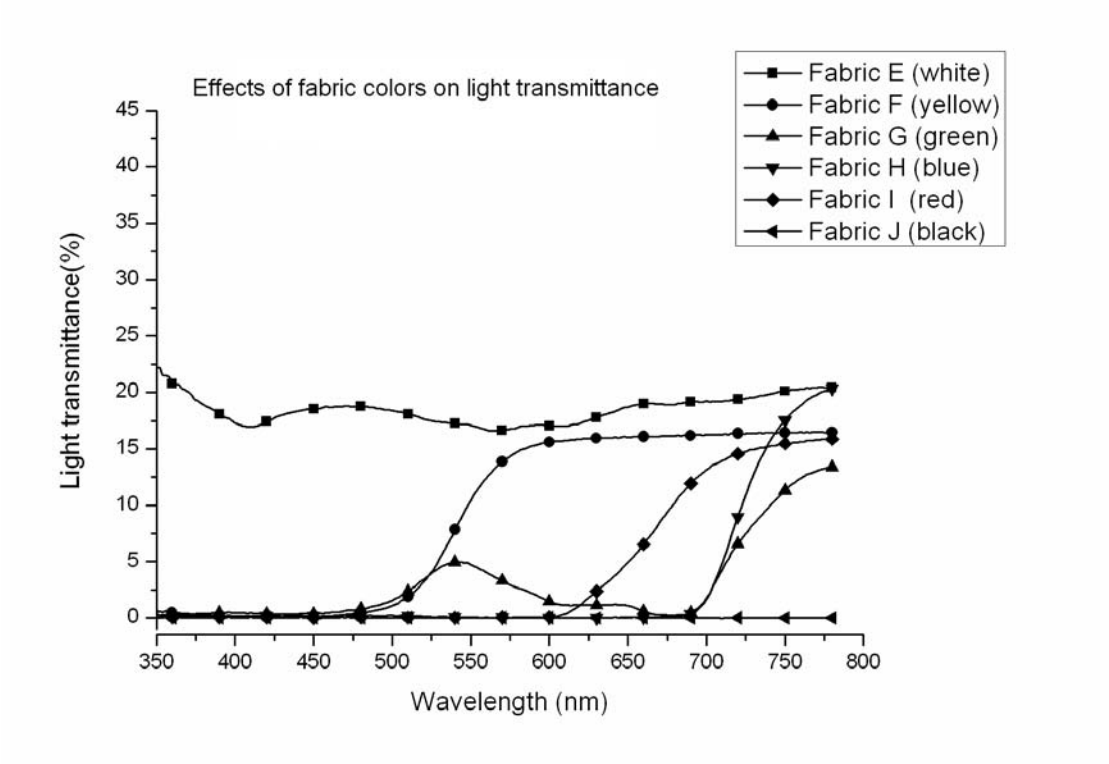


Figure 5-3: Light transmittance of the 6 fabrics of different colors

As shown above, black heavy woven fabrics with high cover factors are effective for photo-protection. Nevertheless, black textile materials are generally not suggested for use in the hospital since it is difficult to check their sanitary conditions. According to Wong's study, black fabrics are also psychologically unpleasant and not accepted by the medical staff and patients in the hospital [68]. Furthermore, there is a potential risk of color staining as dye pigments may be absorbed into the neonate's skin and cause eye infection or hypersusceptibility. In view of this, a three-layer composite structure was designed, with the middle layer made of black woven material for optimum photo-protection, and the inner/outer layer made of white and light materials for the purposes of safety, physiological and psychological comfort, and practical use. The structure and design of the EP are presented in Figure 5-4.

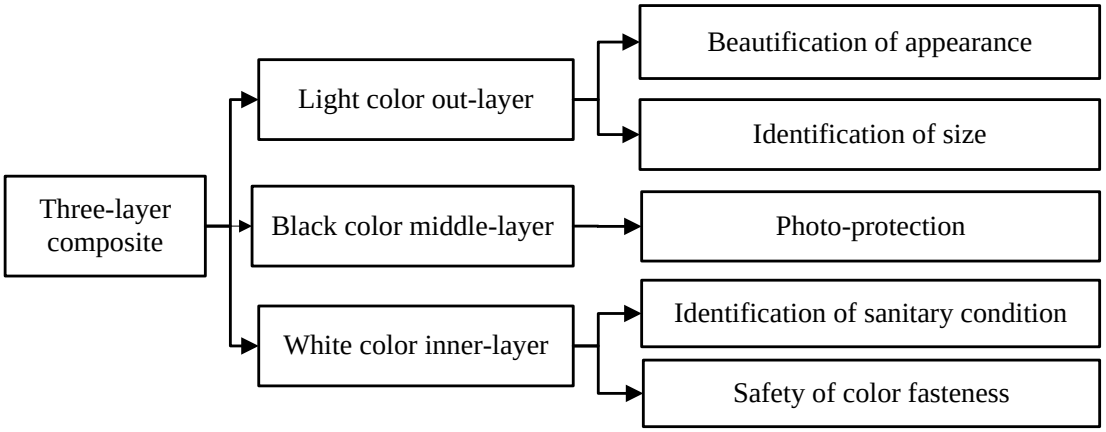


Figure 5-4: Structure and design of the three-layer composite for EPs

5.2.1.2 Prioritization of Fabrication Criteria and Test Methods

Unlike the general and/or home textile and apparel products, the greatest challenge of developing an EP for neonates used in phototherapy treatment lies in not only meeting all the textile product specifications, but also fulfilling the specific requirements for photo-protection in a single best design [48, 60, 61]. To balance the different evaluation criteria for fabric selection, a weighting prioritization matrix approach, which combines subjective and objective measurements, was developed [71, 154, 155]. It is a hybrid method of assigning a weighting and a score to each evaluation criterion. The weighting denotes the importance of a criterion and the score denotes the performance of a fabric sample by a number of subjective and/or objective measurements. Based on the weighting and score, the total weighting index score of the fabric was calculated by the following equation:

$$y = \sum_{i=1}^{n} (a_i * \sum_{j=1}^{k} \frac{x_{ij}}{k}) \quad (5\text{-}1)$$

where y is the total weighting index score, i is the item of the fabric criterion (I = 1,….,n), and j is the item of indices to represent the ability of this fabric criterion (j = 1,…, k). a_i is the important weighting of i fabric criterion, and x_{ij} is the score of fabric performance.

To determine the evaluation criteria and their level of importance (weightings), a 9-point scale questionnaire survey was conducted [99]. The evaluation criteria, including photo-protection, breathability, safety, handfeel, and construction of the inner/outer layer, the middle layer and the composite, were ranked respectively. 8 paediatric medical staff in charge of phototherapy treatment in the SCBU of QMH, and 4 textile experts from the Institute of Textiles and Clothing, The Hong Kong Polytechnic University, were invited to do this survey. Based on the survey results obtained from the 12 medical and textile professionals, 5 major criteria were established for fabrication of the middle layer and the composite structure. They are photo-protection, breathability, safety, handfeel, and construction. Meanwhile, apart from photo-protection, the 4 other evaluation criteria are recommended for fabrication of the inner/outer layer. The weightings for each of the criteria were determined by Equation 5-2.

$$y_i = \frac{(\sum_{j=0}^{7} j \times x_j) / m_i}{\sum_{i=1}^{n} \left(\sum_{j=0}^{7} j \times x_j \right) / m_i} \qquad (5\text{-}2)$$

y_i is the weighting of criterion i (I = 1,...,n); j is rank (j = 0,..., 7); x_j is the number of

respondents selecting this rank; m_i is the number of respondents conducting ranking in criterion *i*. The results of weighting for each criterion are shown in Table 5-2.

Table 5-2: Weighting & importance of fabrication criteria for eye-patch panel of EP_n

Evaluation criteria	Weighting & importance		
	Inner/outer-layer	Middle-layer	3-layer Composite
Photo-protection	-	0.23	0.21
Handfeel	0.28	0.18	0.21
Breathability	0.26	0.22	0.20
Safety	0.23	0.18	0.20
Construction	0.23	0.19	0.18
Total	1.00	1.00	1.00

Among the 5 evaluation criteria, photo-protection, breathability, safety, and construction can be quantified by means of various objective measurements. In this study, the performance of photo-protection was measured in terms of residual illuminance and residual irradiance, while breathability was measured in terms of air resistance and water vapor transmission. Flammability and allergy were examined for the purposes of safety. Fabric construction was determined by its weight and thickness. The indices and the test methods/standards in respect to each evaluation criterion are presented in Table 5-3. It should be noted that the clinical allergy test can only be carried out when the most desirable inner/outer-layer fabric (with the highest total weighting index score) is selected to minimize disturbance and potential skin irritation to the neonates.

Based on the results obtained by the above-mentioned objective tests, a score was then assigned to each fabric tested by the mean ($\bar{x}$)-standard deviation (s) approach [64, 70] with the following score assignment principles.

Principle 1: The higher the measured value is, the higher the satisfaction level becomes in the criterion. The score scale is from 1 (the lowest satisfactory) to 9 (the highest satisfactory).

Principle 2: The lower the measured value is, the higher the satisfaction level becomes in the criterion. The score scale is from 1 (the lowest satisfactory) to 9 (the highest satisfactory).

Principle 3: Either satisfaction or dissatisfaction is in the criterion. The score is either 1 (dissatisfactory) or 9 (satisfactory).

Table 5-3: Evaluation criteria, indices for criteria and related test methods/standards for eye-patch panel of EP_n

Fabric criteria	Indices for criteria			Methods/Standards	Score assignment principles
	Indices	Symbol	Unit		
Photo-protection	Residual illuminance	Ev	lux	ASTM 183-2004	Principle 2
	Residual irradiance	E	µw/cm2/nm		Principle 2
Breathability	Air resistance	AR	kpa.s/m	KES-F8-AP1	Principle 2
	Water vapor transmission	WVT	$g/m^2.hr$	ASTM E96/E96M-05	Principle 1
Safety	Flammability	F	-	ASTM D 1230-94	Principle 3
	Allergy	A	-	Kwok (Kwok, 1992)	Principle 3
Construction	Weight	W	g/m^2	ASTM D 3776-96	Principle 2
	Thickness	T	mm	ASTM D 1777-96	Principle 2

For instance, on the basis of Principle 1, a fabric with a higher value of water vapour transmission (WVT) has a higher score value and a higher satisfactory level since it is highly breathable. By contrast, a fabric with a higher value of residue illuminance (Ev) and residual irradiance (E) allows a higher light transmission and therefore provides a lower level of eye protection. In view of this, Principle 2 is

applied and the fabric results in a lower score value and a lower satisfactory level. Principle 2 is also used for air resistance (AR), weight (W) and thickness (T) since low air-resistant, light and thin fabrics are generally more preferable. Principle 3 is only applied to flammability (F) and allergy (A) as fabrics can only pass (score of 9) or fail (score of 1) the safety tests.

5.2.1.3 Materials Tested

Natural materials such as cotton give a very comfortable handfeel for skin contact because of its high absorbency, softness, good heat conductivity, and good electrical conductivity. They have no surface characteristics that irritate skin. Cotton has a moisture regain of 7% to 11% and the fibers absorb moisture and feel good against skin in high humidity.

Made of regenerated materials, rayon is comfortable, smooth, soft, and absorbent. Rayon has a moisture regain of 11.5% to 12.5%, eliminates static, and avoids skin irritation. Lyocell is another soft, smooth fiber, generally used for making comfortable apparel and furnishings. It has a moisture regain of 11.5%. Due to its softness and high absorbency, lyocell is ideal for apparel production, especially close-fitting apparel.

Synthetic materials such as polyester are seldom used for close-fitting medical textile products due to less favourable handfeel and low absorbency that may cause skin allergies. Nevertheless, the new synthetic fibers, such as thermoplastic

polyurethane-polyethylene (TPU-PE) with excellent handfeel, are becoming increasingly popular for producing medical apparel items; spandex blended fabrics are also commonly used for medical items, such as bandages and surgical wraps.

In this study, a total of 18 fabrics, including woven, knitted, and non-woven, are examined. The fabrics are 100% cotton, cotton/spandex blended, cotton/Modal® (lyocell) blended, Modal® (lyocell)/spandex blended, rayon/spandex blended, 100% polyester, or 100% TPU-PE. Among the examined fabrics, 12 of them were selected for the inner/outer layer and 10 for the middle layer. 4 fabrics, including OW-2/MW-1, OW-3/MW-3, OK-1/MK-1, and OK-4/MK-2, were chosen for both the inner/outer layer and the middle layer. The specifications of the inner/outer-layer and middle-layer fabrics are presented in Tables 5-4 and 5-5 respectively.

Table 5-4: Specifications of inner/outer-layer fabric samples

Fabric No.	Content	Construction	Weight (g/m^2)	Thickness (mm)	Yarn count		Fabric count	
					Warp (tex)	Weft (tex)	Ends(or wale)/cm	Picks(or course)/cm
OW-1	100% Cotton	Woven (plain)	72.74	0.20	7.3	7.3	60.2	36.8
OW-2	96% Cotton 4% Spandex	Woven (plain)	146.6	0.37	14.5	14.5	62.8	22.6
OW-3	96% Cotton 4% Spandex	Woven (1/2 twill)	180.6	0.39	19.7	19.7	68.1	21.1
OW-4	97% Cotton 3% Spandex	Woven (2/2 twill)	240.8	0.47	18.0	18.0	69.2	29.8
OK-1	100% Cotton	Knitted	100.8	0.54	14.5		15.9	17.8
OK-2	50% Cotton 50% Modal	Knitted	120	0.53	18.0		34.9	19.8
OK-3	95% Modal 5% Spandex	Knitted	207.6	0.68	14.5		17.0	26.8
OK-4	95% Cotton 5% Spandex	Knitted	207.6	0.81	14.5		18.2	27.2
OK-5	95%Rayon 5% Spandex	Knitted	230.0	0.70	18.0		15.1	23.4
ON-1	100% Polyester	Non-woven	79.9	0.58	-		-	-
ON-2	TPU-PE	Non-woven	80.0	0.39	-		-	-
ON-3	TPU-PE	Non-woven	120.0	0.58	-		-	-

Table 5-5: Specifications of middle-layer fabric samples

Fabric No.	Content	Construction	Weight (g/m2)	Thickness (mm)	Yarn count		Fabric count	
					Warp (tex)	Weft (tex)	Ends(or wale)/cm	Picks(or course)/cm
MW-1	96% Cotton 4% Spandex	Woven(plain)	146.6	0.37	14.5	14.5	62.8	22.6
MW-2	100% Cotton	Woven(plain)	266.9	0.60	49.0	28×2	25.4	16.3
MW-3	96% Cotton 4% Spandex	Woven (1/2 twill)	180.6	0.39	19.7	19.7	68.1	21.1
MW-4	96% Cotton 4% Spandex	Woven (1/2 twill)	240.8	0.50	36.9	36.9	44.4	15.7
MW-5	100% Cotton	Woven (2/2 twill)	316.7	0.79	55.0	86.0	31.6	15.5
MK-1	100% Cotton	Knitted	100.8	0.54	14.5		15.9	17.8
MK-2	95% Cotton 5% Spandex	Knitted	207.6	0.81	14.5		18.2	27.2
MK-3	95% Cotton 5% Spandex	Knitted	258.0	1.19	18.0		15.9	24.4
MN-1	100% Polyester	Non-woven	53.0	0.45	-		-	-
MN-2	36.7% Wool 63.3% Rayon	Non-woven	160.0	1.24	-		-	-

5.2.1.4 Results and Discussions

(a) Objective Evaluation Results

The objective evaluation results of inner/outer-layer and middle-layer fabrics are presented in Tables 5-6 and 5-7 respectively.

Table 5-6: Objective evaluation results of inner/outer-layer fabrics

Indices	OW-1	OW-2	OW-3	OW-4	OK-1	OK-2	OK-3	OK-4	OK-5	ON-1	ON-2	ON-3
AR	0.14	1.37	3.33	1.92	0.06	0.10	0.16	0.49	0.37	0.07	0.16	0.33
WVT	25.91	24.91	24.87	24.96	25.11	25.64	28.01	25.20	30.67	23.60	24.10	24.14
F	C-2	C-1	C-1	C-1	C-1	C-1	C-1	C-1	C-1	C-1	C-1	C-1
W	72.70	146.60	180.60	240.80	100.80	120.00	207.60	207.60	230.00	79.90	80.00	120.00
T	0.20	0.37	0.35	0.47	0.54	0.53	0.68	0.81	0.70	0.58	0.39	0.52

Remarks: AR: Air resistance (kpa.s/m); WVT: Water vapor transmission (g/m2.hr);
F: Flammability (Class 1(C-1)-Class 3 (C-3));
W: Weight (g/m^2); T: Thickness (mm)

Table 5-7: Objective evaluation results of middle-layer fabrics

Indices	MW-1	MW-2	MW-3	MW-4	MW-5	MK-1	MK-2	MK-3	MN-1	MN-2
Ev	12.601	2.804	2.802	3.400	2.597	156.801	12.203	3.601	311.00	6.202
E	0.0272	0.0016	0.0016	0.0026	0.0024	0.4648	0.0050	0.0002	1.0828	0.0130
AR	1.34	3.05	3.28	1.59	1.29	0.06	0.54	1.66	0.03	0.11
WVT	24.91	23.92	24.87	26.56	24.39	25.10	25.20	25.98	26.92	27.49
F	C-1	C-1	C-1	C-1	C-1	C-1	C-1	C-1	C-1	C-1
W	146.60	266.90	180.60	240.80	316.70	100.80	207.60	258.00	53.00	171.00
T	0.36	0.60	0.39	0.50	0.79	0.54	0.83	1.19	0.45	1.24

Remarks: Ev: Residual illuminance (lux); E: Residual irradiance (μw/cm2/nm);
AR: Air resistance (kpa.s/m); WVT: Water vapor transmission (g/m^2.hr);
F: Flammability (Class 1(C-1)-Class 3 (C-3)); W: Weight (g/m^2); T: Thickness (mm)

(b) Subjective Handfeel Results

Subjective assessment of fabric handfeel was conducted and a multiple regression model was developed based on subjective questionnaire surveys and objective measurements using the Kawabata Evaluation System for Fabrics (KES-F) well-known for evaluating fabric handfeel [156, 157]. The 18 fabrics were independently assessed for handfeel by textile and medical professionals using a 9-point scale questionnaire. The number of evaluation panels was calculated by the follow equation [158]:

$$n = \frac{4p(100-p)}{l^2} \tag{5-3}$$

where n is the number of experts involved, p is the percentage time spent on the activity, and l is the variation expressed as a percentage. In this evaluation, p = 2 for accuracy at a 95% confidence interval and l = 4. Therefore, n = 49. A total of 52 textile and medical professionals were invited to do the survey. The total mean rating

of handfeel and the standard deviation of the panel's assessment of handfeel are given in Table 5-8.

Table 5-8: The total mean rating and standard deviation of subjective assessment of handfeel for each fabric

Fabric No.	Total mean rating	Standard deviation
OW-1	5.81	1.61
OW-2	5.08	1.59
OW-3	4.81	1.58
OW-4	4.31	1.60
OK-1	6.81	1.14
OK-2	7.42	0.98
OK-3	8.00	1.14
OK-4	6.02	1.41
OK-5	6.87	1.30
ON-1	4.73	2.04
ON-2	6.10	2.32
ON-3	5.73	2.44
MW-2	3.44	1.65
MW-4	3.73	1.54
MW-5	3.92	1.81
MK-3	5.83	1.41
MN-1	4.77	2.23
MN-2	4.33	1.78

Remarks: 9-excellent; 7-good; 5-average; 3-below average; 1-Poor

The average correlation coefficient ($\bar{r}$) between each judge's handfeel rating and the total mean rating of the 52 professionals were calculated to estimate the consistency of each judge's assessment of handfeel. The results demonstrate that the level of consistency is relatively high ($\bar{r}$ = 0.69) and the level of subjective assessment is reliable.

To study the relationship between subjective and objective measurements, a linear regression analysis was applied by the total mean rating of handfeel from the 52 experts as a dependent variable to measure the relationship against the 15 indices

measured by the KES system. The correlation coefficient values and the significant level values are shown in Table 5-9. The significant level values in ANOVA of seven indices, including EMT, RT, G, 2HG, 2HG5, B and 2HB, were less than 0.05. Above results exhibited a certain degree of correlation with the subjective assessment of handfeel value (the correlation coefficient ranging from 0.525 to 0.748). According to the above-mentioned results, the mechanical properties of tensile, shearing and bending seem to be the most influential properties of handfeel. The slope of linear regression equation (*b*) of G, 2HG, 2HG5, B and 2HB were negative, suggesting that when the values of G, 2HG, 2HG5, B, and 2HB are higher, the ratings of handfeel assessment become lower.

Table 5-9: Results of linear regression of indices

Independent variables	Correlation coefficient (r)	Significant level in ANOVA	Slope of regression (*b*)
EMT (Tensile extensibility)	**0.670**	0.002	0.038
LT (Linearity of load/extension curve)	0.354	0.15	3.947
WT (Tensile energy)	0.259	0.299	-0.039
RT (Resilience of tensile)	**0.546**	0.019	0.064
G (Shear rigidity)	**0.789**	0	-0.727
2HG (Hysteresis of shear force at 0.5º)	**0.593**	0.009	-0.329
2HG5(Hysteresis of shear force at 5º)	**0.778**	0	-0.218
B (Bending rigidity)	**0.728**	0.001	-4.437
2HB (Hysteresis of bending moment)	**0.717**	0	-5.703
LC ((Linearity of compression curve)	0.108	0.669	1.577
WC (Compressional energy)	0.139	0.581	1.247
RC (Compressional resilience)	0.066	0.796	-0.012
MIU (Frictional coefficient)	0.348	0.157	4.328
MMD (Mean deviation of Miu)	0.366	0.135	-68.241
SMD (Surface roughness)	0.052	0.836	-0.026

The following model was formulated by the multiple linear regression analysis

with the seven indices as independent variables and the total mean ratings as dependent variables:

$$y = 5.246 + 0.022x_{EMT} + 0.012x_{RT} - 2.033x_{G} + 0.526x_{2HG} + 0.365x_{2HG5} + 8.464x_{B} - 15.520x_{2HB} \quad (5\text{-}4)$$

Above mathematical model had a strong correlation coefficient R (R = 0.929) and a strong R square (R^2 = 0.863). The significant level was 0.001. It showed that this model reflects a highly significant regression. The values of subjective assessment of handfeel and the predicted handfeel are presented in Table 5-10. The results of paired-samples T test show that the subjective assessment of handfeel and the predicted handfeel had no significant difference (p = 0.000 < 0.05) (see Table 5-11). It is concluded that the model is effective to predict handfeel.

Table 5-10: Comparison of total mean rating of handfeel and predict handfeel

Fabric No.	Total mean rating of handfeel (a)	Predict handfeel (b)
OW-1	5.81	5.63
OW-2	5.08	4.56
OW-3	4.81	5.02
OW-4	4.31	4.81
OK-1	6.81	6.62
OK-2	7.42	6.64
OK-3	8.00	7.84
OK-4	6.02	6.57
OK-5	6.87	7.06
ON-1	4.73	5.22
ON-2	6.10	6.40
ON-3	5.73	5.65
MW-2	3.44	3.11
MW-4	3.73	4.05
MW-5	3.92	5.09
MK-3	5.83	5.25
MN-1	4.77	4.70
MN-2	4.33	3.95
Remarks: 9-excellent; 7-good; 5-average; 3-below average; 1-Poor		

Table 5-11: Results of paired samples T test

Paired samples	N	Correlation	Sig.
Total mean rating of handfeel & Predict handfeel	18	0.928	0.000

(c) Total Weighting Index Scores for Fabric Selection

By using the weighting prioritization matrix approach formulated in Equation 5-1, the total weighting index score for each fabric was calculated. The assigned scores and the total weighting index scores of inner/outer-layer and middle-layer fabrics are shown in Tables 5-12 and 5-13 respectively.

Table 5-12: Assigned scores and total weighting index scores (inner/outer-layer)

Evaluation criteria	Weighting	Indices	OW-1	OW-2	OW-3	OW-4	OK-1	OK-2	OK-3	OK-4	OK-5	ON-1	ON-2	ON-3
Handfeel	0.28	THV	6	5	5	4	7	7	8	6	7	5	6	6
Breathability	0.26	AR	6	4	1	3	6	6	6	5	6	6	6	6
		WVT	5	4	4	4	5	5	7	5	9	3	3	3
Safety	0.23	F	5	9	9	9	9	9	9	9	9	9	9	9
Construction	0.23	W	7	5	4	2	7	6	3	3	2	7	7	6
		T	9	7	7	5	5	5	3	1	3	4	6	5
Total weighting index score			6.10	5.89	5.39	4.91	**6.84**	**6.73**	6.69	5.51	6.56	5.91	6.42	6.19

The results indicated that knitted fabrics (i.e. OK-1，2，3，4, and 5) generally had higher scores (7 or 8) in handfeel than the other woven and non-woven samples. As far as breathability is concerned, the knitted fabrics also got higher scores (5 to 9 at AR and WVT) than the woven fabrics (OW-1, 2, 3, and 4 with scores of 1 to 6) and the non-woven fabrics (ON-1, 2, and 3 with scores of 3 to 6). The results are somewhat expected because knitted fabrics are used for most of the close-fitting garments, especially underwear. Regarding safety, among the 12 fabrics, only OW-1 failed the flammability test and had a score of 5. Regarding construction, OW-1 had the highest score of 9 in thickness and 7 in weight. Samples OW-2, OW-3, OK-1, OK-2, ON-1, ON-2, and ON-3 received moderate scores of 5.5 to 6.5 (average scores of W and T), and OW-4, OK-3, OK-4, and OK-5 got low scores of 2 to 3.5 (average scores of W and T).

The total weighting index scores indicate that OK-1 and OK-2 achieve the highest scores (6.84 and 6.73 respectively) among the 12 inner/outer-layer fabrics. The allergy tests were subsequently conducted for neonates with OK-1 and OK-2 and the results show that both samples did not cause allergies. It can be concluded that OK-1 and

OK-2 are the most appropriate fabrics for the inner/outer layer of the composite for EP development.

Table 5-13: Assigned scores and total weighting index scores (middle-layer)

Evaluation criteria	Weight-ing	Indices	MW-1	MW-2	MW-3	MW-4	MW-5	MK-1	MK-2	MK-3	MN-1	MN-2
Photo-protection	0.23	Ev	2	6	6	6	6	1	2	6	1	5
		E	2	6	6	6	6	1	5	6	1	4
Handfeel	0.18	THV	5	3	5	4	4	7	7	5	5	4
Breathability	0.22	AP	5	2	2	4	5	7	6	4	7	7
		WVT	4	2	4	7	3	4	4	6	7	8
Safety	0.18	F	9	9	9	9	9	9	9	9	9	9
Construction	0.19	W	6	3	5	4	2	7	5	3	8	6
		T	7	5	7	6	4	6	4	2	6	1
Total weighting index score			5.21	4.74	**5.70**	**5.88**	5.17	5.56	5.64	5.48	5.62	5.69

Table 5-13 presents the weighting index scores for the 10 middle-layer fabrics studied in this research. The results indicate that all the light fabrics, including MW-1, MK-2, MK-3, MN-1, and MN-2, received low scores in photo-protection (Ev and E). In contrast, the moderately heavy and heavy fabrics (MW-2, MW-3 MW-4, MW-5, and MK-3) achieved high scores in photo-protection. Knitted fabrics generally gave better handfeel performance than the woven and non-woven samples. All 10 tested fabrics, passed the flammability test and received a score of 9. Regarding construction, MW-1, MW-3, MW-4, MK-1, and MN-1 had high scores as they are generally light and thin. As a result, MW-3 and MW-4 obtained the highest total weighting index scores (5.70 and 5.88 respectively) among the 10 middle-layer fabrics. Therefore, they are suggested for the middle layer of the composite for EP_n development.

5.2.1.5 Evaluation of the Three-layer Composites

Six 3-layer composites were constructed by the two inner/outer-layer fabrics (OK-1 and OK-2) and the two middle-layer fabrics (MW-3 and MW-4) as listed above. The assembly of the composites is shown in Table 5-14 and their structure is presented in Figure 5-5.

Table 5-14: Assembly of composites constructed by selected single-layer fabrics

Structure	C1	C2	C3	C4	C5	C6
Inner-layer	OK-2	OK-1	OK-2	OK-2	OK-1	OK-2
Middle-layer	MW-3	MW-3	MW-3	MW-4	MW-4	MW-4
Outer-layer	OK-2	OK-1	OK-1	OK-2	OK-1	OK-1

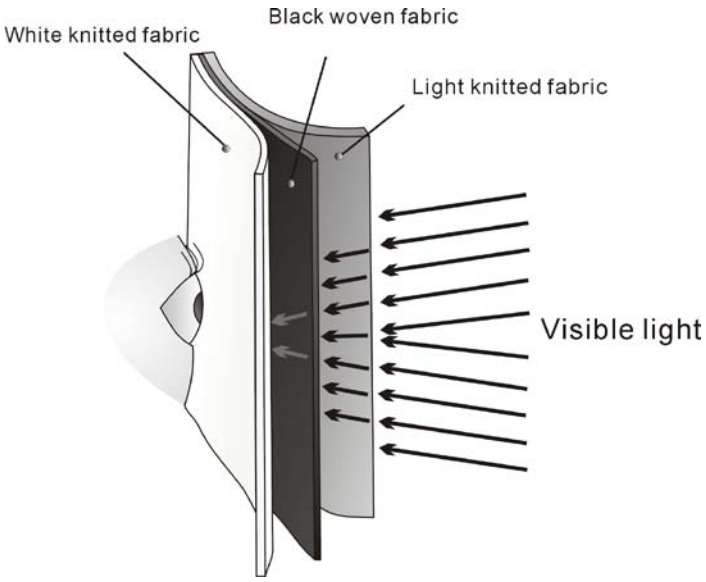


Figure 5-5: Structure and function of composites for eye-patch panel

Similarly, the weighting prioritization matrix approach used for performance evaluation was adopted to examine the 6 composites. Photo-protection, breathability, handfeel, safety, and construction of the composites were evaluated and compared with the performance of EP_1 that is commonly used in the hospital. EP_1 also has a

3-layer structure, composed of white knitted nylon (as outer layer), dark grey polyurethane foam (as middle layer), and white knitted cotton (as inner layer). Composite indices, including photo-protection, breathability, safety, and construction, were objectively measured based on the standards/methods listed in Table 5-6. Regarding handfeel, the 6 composites were assigned scores obtained by the inner-layer fabrics, while handfeel of EP_1 was determined by the assessment of the panel who also conducted subjective assessment for the single-layer fabrics. Thus, eligible fabrics were confirmed by comparing them with the fabric of EP_1. The overall results of the total weighting index scores are presented in Table 5-15 (see objective measurements in Appendix 3).

Table 5-15: Assigned scores and total weighting index scores of composites for EP_1 and for EP_n

Evaluation criteria	Weighting	Indices	C1	C2	C3	C4	C5	C6	EP_1
Photo-protection	0.21	Ev	7	7	7	4	3	3	1
		E	7	7	7	3	3	3	1
Handfeel	0.21	THV	7	7	7	7	7	7	6
Breathability	0.2	AP	3	3	3	6	7	7	9
		WVT	4	3	4	7	6	7	9
Safety	0.2	F	9	9	9	9	9	9	9
		A	9	9	9	9	9	9	9
Construction	0.18	W	6	8	7	2	4	3	9
		T	6	7	7	2	4	3	1
Total weighting index score			6.52	6.69	**6.70**	5.67	5.92	5.84	5.97

Amongst the composites for EP_n and EP_1, the total weighting index score of the composite for EP_1 is lower than that of C1, C2 or C3. Nevertheless, the composite for EP_1 has excellent breathability and is light in weight because the density of the middle

layer is low (0.0453 m^3), which can be attributed to its porousness. The thickness of the composite for EP_1 (3.75 mm) is much higher than that of the 6 new composites (<1.45 mm). The results of the bending test by the KES-FB-2 show that the bending rigidity of the composite for EP_1 (2.02 gf.cm2/cm) is higher than that of all new composites (< 0.69 gf.cm2/cm). High bending rigidity causes high stiffness of the fabric. This property of the composite for EP_1 can explain why it fits on the neonatal face poorly. The low stiffness of the new composites can improve the fitting performance of EP_n. The scores for handfeel are similar since the inner-layer fabrics for both the composite for EP_1 and the new composites are cotton or cotton/Modal® blended knitted. The total weighting index scores indicate that the score of the composite for EP_1 (5.97) is lower than that of C1 (6.52), C2 (6.69) or C3 (6.70) while C3 obtains the highest index score. As a result of the evaluation above, C3 is recommended for the eye-patch panel of EP_n to meet the requirements for the EP used in phototherapy.

5.2.2 Selection of Fastening System of EP_n

Kannermeyer defined a fastening system as “any method (either inherent in the composition of the materials or applied) which is utilized to permanently or temporarily join elements together.” [159]

A fastener is often a critical element that determines whether a garment functions properly. It not only controls how a garment works, but also affects a garment’s shape

and appearance [48]. A fastening system accomplishes a wide variety of tasks. It gives shape and form to a garment, helps the wearer get in and out of a garment quickly and easily, and/or is used for adjustment or fitting purposes. To achieve optimum comfort and functional performance of EP_n in the neonatal unit, an appropriate fastening system must be selected carefully.

5.2.2.1 Selection of Bandage-type Elastic Materials

a) Material Tested

Similar to the design of hair bands or diapers, elastic bands are used to hold the EP in a position securely and comfortably. The EP can also fit snugly on the neonate's eyes with minimum pressure. Elastic bands are adopted by both EP_1 and EP_2. However, the elastic band used in the EP_1 is only 17 mm wide and 15 mm long. The limited width is unable to fit different sizes and shapes of the neonate's head. The non-woven elastic band of EP_2 has a large panel to enhance the fitting. Therefore, a patented bandage-type non-woven elastic material with a large width of 75 mm was sourced from Jiangyin Changsen Nonwoven Science Co. Ltd. for the development of EP_n [18]. This bandage-type non-woven elastic material is a composite with its outer/inner layers made of crumpled non-woven fabric and the middle layer of latex thread. The structure is shown in Figure 5-6. Its performance was evaluated and compared with the bandage-type material used in EP_2.

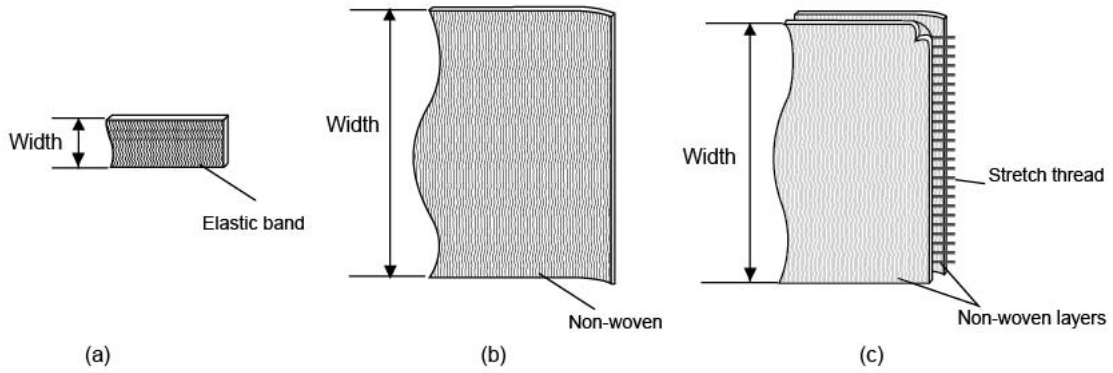


Figure 5-6: Bandage-type elastic materials for (a) EP_1, (b) EP_2 and (c) EP_n

The specifications of the bandage-type materials for EP_2 and EP_n are presented in Table 5-16.

Table 5-16: Specifications of bandage-type materials of EP_2 and EP_n

Materials	Construction			Content	Weight (g/m^2)	Thickness (mm)
EP_2	Crumpled non-woven			Polypropylene	155.00	2.01
EP_n	Composite	Inner/ outer	Crumpled non-woven	Polyethylene/ polypropylene	120.00	2.30
		Middle	Stretch	Latex		

b) Test Methods

By referring to fabrication of the inner/outer layer materials for the eye-patch panel, the evaluation criteria for elastic band were handfeel, breathability, safety, and construction. The weighting of the criteria was determined by a 9-scale questionnaire survey. The subjective handfeel assessment was carried out while others indices were measured using objective methods. The evaluation criteria, weighting and objective evaluation standard/method are presented in Table 5-17.

Table 5-17: Evaluation criteria, weighting and objective evaluation standards/methods for bandage-type elastic materials

Fabric criteria	Weighting	Indices for criteria			Methods/standard	Score assignment principles
		Indices	Symbol	Unit		
Handfeel	0.28	Subjective assessment	-	-	-	Principle 1
Breathability	0.26	Air resistance	AR	kpa.s/m	KES-F8-AP1	Principle 2
		Water vapor transmission	WVT	$g/m^2.hr$	ASTM E96/E96M-05	Principle 1
Safety	0.23	Flammability	F	-	ASTM D 1230-94	Principle 3
		Allergy	A	-	Kwok (Kwok, 1992)	Principle 3
Construction	0.23	Weight	W	g/m^2	ASTM D 3776-96	Principle 2
		Thickness	T	mm	ASTM D 1777-96	Principle 2

The subjective evaluation of handfeel of bandage-type elastic materials was conducted by a questionnaire survey. A 9-point scale was used in the questionnaire with a score of 9 denoting the best hand feel while a score of 1 denoting the worst. The respondents of the questionnaire survey included 4 textile experts and 8 medical staff.

c) Results and Discussion

The results of subjective assessment are presented in Table 5-18. Based on the results obtained from 14 respondents, the mean rating of bandage-type elastic materials for EP_n are higher than that of EP_2.

Table 5-18: Subjective evaluations of handfeel of bandage-type elastic materials

Scale	EP_2	EP_n
Mean of rating	6.17	6.75

It is noted that the bandage-type elastic materials of both EP_2 and EP_n were tested by the KES-F. The results are presented in Table 5-19. Results reveal that bandage-type elastic material of EP_n has better extensibility, better softness, lower stiffness, and lower roughness, indicating that EP_n uses better elastic band materials in terms of handfeel than EP_2.

Table 5-19: Objective measurements of handfeel of bandage-type elastic materials

Indices	Symbol	Unit	Objective measurements	
			EP_2	EP_n
Tensile resilience	RT	%	58.46	57.49
Extensibility	EMT	%	28.1	47.89
Shear rigidity	G	gf/cm.degree	2.43	1.18
Bending rigidity	B	$gf.cm^2/cm$	0.90	0.65
Compressibility	EMC	gf/cm2	27.31	34.8
Compressional resilience	RC	%	45.28	45.55
Frictional coefficient	MIU	-	0.36	0.38
Roughness	SMD	-	11.91	10.83

Both subjective and objective measurement results are summarized in Table 5-20.

Table 5-20: The total weighting index scores for bandage-type elastic materials

Evaluation criteria	Weighting	Indices	Evaluation values		Assigned scores	
			EP_2	EP_n	EP_2	EP_n
Handfeel	0.28	-	6.17	6.75	1	9
Breathability	0.26	AP	0.25	0.04	1	9
		WVT	48.10	27.51	9	1
Safety	0.23	F	C1	C1	9	9
		A	Non-allergy	Non-allergy	9	9
Construction	0.23	W	155.00	120.00	1	9
		T	2.01	2.30	9	1
Total Weighting Index Score					4.80	**7.04**

As shown in Table 5-20, the total weighting index score of bandage-type elastic materials of EP_n (7.04) is higher than that of EP_2 (4.80). The bandage-type elastic materials of EP_n have many characteristics, such as good handfeel, excellent breathability, safety, and light weight. And they are slightly thicker than those of the EP_2. Thus, the bandage-type materials of the EP_n should be applied to EP_n development.

5.2.2.2 Selection of Hook-and-loops

The hook-and-loop tape is developed as a touch fastener. It consists of a pair of polyamide tapes, one covered by tiny hooks and the other by tiny loops. The two tapes are closed by touch and pressure, and opened or separated by peeling action. Hook-and-loop tapes have many uses and, are often used for clothing for children and people with disabilities for ease of opening and closing [48].

By referring to the questionnaire survey for current EPs in Section 3.3 of Chapter 3, hook-and-loop fasteners used by current EPs are accepted and recommended for EP_n development. In this study, a hook-and-loop fastener manufactured by the "Velcro" company is recommended because of its wide application to neonatal and children products.

a) Materials Tested

The specifications of the hook-and-loop fasteners on the back band of EP_1 and

EP_2, and the specifications of the collected hook-and-loop fasteners for EP_n are presented in Table 5-21.

Table 5-21: Specifications of hook-and-loop fasteners

Fasteners	Loop			Hook			
	Content	Weight (g/m^2)	Thickness (mm)	Content	Weight (g/m^2)	Thickness (mm)	Density ($hook/mm^2$)
EP_1	Nylon	125.44	0.70	Nylon	387.18	1.38	0.72
EP_2	Polypropylene	155.00	1.90	Nylon	137.62	0.54	2.56
EP_n	Nylon	150.31	0.83	Nylon	265.82	0.66	2.64

b) Test Methods

Hook-and-loop tapes are more functionally important than aesthetically. The holding power is affected by the pressure applied to the tapes, the structure of the tapes, and the application to the garments. The performance of a hook-and-loop tape is determined by T peel strength and shear strength. T peel strength is a measure of force to pull the two tapes apart from one end. Shear strength is the force required to make the two parts slide on each other and separate the tapes. The durability of hook-and-loop tapes is determined by holding power tests and appearance checks after a specified number of opening and closing cycles. One of the main problems is that the hook side tends to attach to other materials or garment parts. The scratchy hooks collect lint after a time and become non-functional [48].

The evaluation criteria are security, easy handling, and comfort. The weightings for the criteria were calculated based on 9-scale questionnaire survey. Weightings of evaluation criteria, related indices, and test methods/standards for the hook-and-loop fasteners are presented in Table 5-22. As the size of hook-and-loop fasteners for the

current EPs is limited, the sample size for the EP_1, EP_2 and EP_n was adjusted to 15 mm (width) × 45 mm (length) in shear strength, T peel strength, and hardness tests.

Table 5-22: Evaluation criteria, indices for criteria and test methods/standards for hook-and-loop fasteners

Fabric criteria	Weighting	Indices for criteria		Methods/standard	
		Indices	Unit	Objective measurement	Subjective assessment
Security	0.40	Shear strength	N/mm	ASTM D 5169-98	Survey
Ease handling	0.30	T peel strength	N/mm	ASTM D 5170-98	Survey
Comfort	0.30	Hardness	° ShD	ASTM D 2240-05	Survey
		Handfeel	-	-	Survey

Meanwhile, all above-mentioned indices were assessed by a 9-scale questionnaire survey. The score of 9 denoted the best while the score of 1 denoted the worst. The respondents of the questionnaire survey were 4 textile experts and 8 medical staff. Meanwhile, shear strength, T peel strength, and hardness were measured by objective methods.

c) Results and discussions

The results of subjective assessments of hook-and-loop fasteners and the calculated total weighting index scores are presented in Table 5-23. It shows that the hook-and-loop fastener of EP_n obtained the highest total weighting index score.

Table 5-23: Score and total weighting index scores of hook-and-loop fasteners

Criteria	Weighting	Indices		EP_1	EP_2	EP_n
Security	0.40	Shear strength		6	2	8
Easy handling	0.30	T peel strength		5	6	5
Comfort	0.30	Hardness		7	7	9
		Handfeel	Loop	6	6	7
			Hook	4	8	7
Total weighting index score				5.60	4.70	**6.90**

The objective measurement results of shear strength, T peel strength and hardness of hook-and-loop fasteners are presented in Table 5-24. It shows that the hook-and-loop fastener of EP_n obtained the highest value of maximum load of shear strength (4.40 N/mm) while that of EP_2 obtained the lowest value (0.35 N/mm). The results show that the security of the hook-and-loop fastener of EP_n is the best whilst that of EP_2 is the worst. For easy handling, the hook-and-loop fastener of EP_1 obtained the highest value of maximum force of T peel strength (0.49 N/mm) and the value for the EP_n was slightly lower when EP_2 obtained the lowest value (0.22 N/mm). The results indicate that the hook-and-loop fastener of EP_2 is the easiest to handle. For hardness of the composite fixed to hooks, EP_n scored the lowest (71° ShD) whilst EP_1 had the highest score. As indicated by the results, when the neonate's head was pressed by the composite with hooks, EP_n provided the best comfort while EP_2 the worst. Obviously, objective results are consistent with the subjective assessments. Objective results provide objective evidence for the respondents' score assignments. Thus, it is concluded that the hook-and-loop fastener collected from Velcro Company is appropriate for EP_n.

Table 5-24: Comparisons of evaluation of hook-and-loop fasteners for EP_1, EP_2 and EP_n

Criteria	Weighting	Indices		Evaluation values		
				EP_1	EP_2	EP_n
Security	0.40	Shear strength		1.73	0.35	4.40
Ease handling	0.30	T peel strength		0.49	0.22	0.40
Comfort	0.30	Hardness		82	88	71
		Handfeel	Loop	6.25	6.08	7.25
			Hook	4.17	7.50	7.08

5.3 Initial Designs and Prototypes Development

According to the design criteria/specifications and anthropometric/fabrication results, four initial EP prototypes were designed and developed.

5.3.1 Initial EP_n Designs

5.3.1.1 Style 1 of Initial EP_n Design

The design of initial EP_n, Style 1, is presented in Figure 5-7. The design features of Style 1 are shown below:

(1) The eye-patch panel is a 3-layer composite in a rectangular shape with round corners. A U-shape is cut in the middle to accommodate the shape of the nose.

(2) A color binding is used as a size code of the EP to enclose the edges of the eye-patch panel. “Easing” is inserted around the edges so that the EP can fit snugly on the protruding ethmoid bone and nasal septum with minimum light gaps.

(3) The two elastic bands of the fastening system are fixed in the top and bottom right-hand corners of the eye-patch panel. This allows the two bands to bind

around the neonate’s ears.

(4) Two pairs of hook-and-loop tapes are used for binding. The loop side of the tape is sewn on the ends of the two elastic bands, while the hook side is sewn on the eye-patch panel.

The pattern details are presented in Appendix 4.

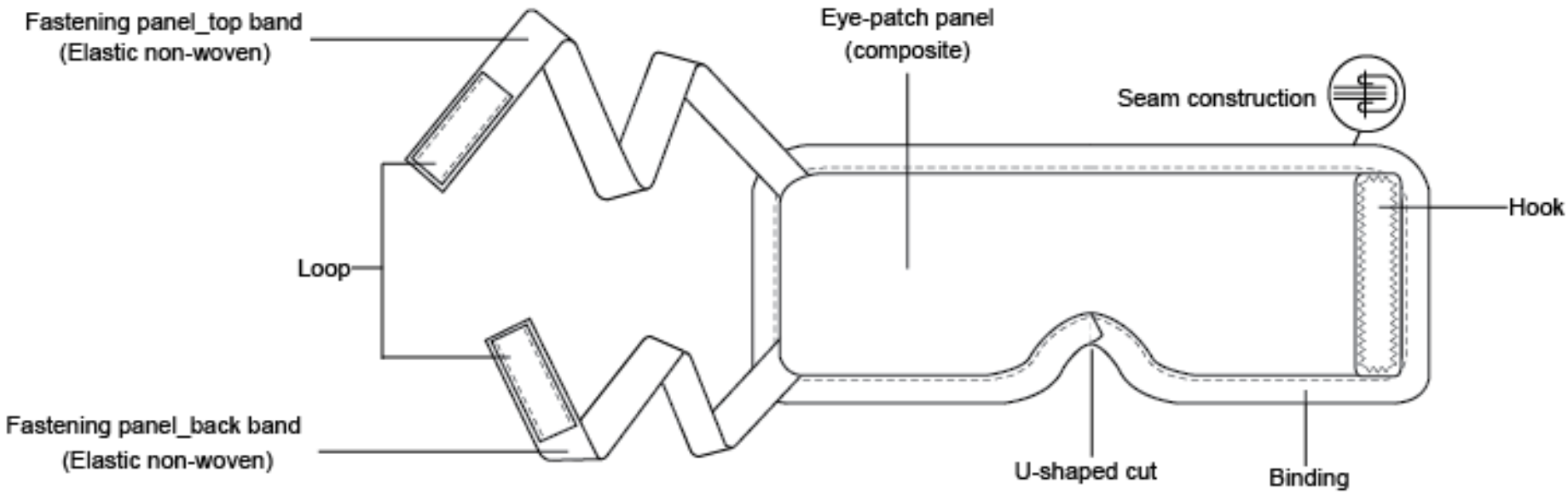


Figure 5-7: Design of Initial EP_n (Style 1)

5.3.1.2 Style 2 of Initial EP_n Design

The design of initial EP_n, Style 2, is presented in Figure 5-8. The design features of Style 2 are shown below:

(1) The eye-patch panel is a 3-layer composite in a rectangular shape with round corners. A U-shape is cut in the middle.

(2) The 3-layer composite is sewn together by zigzag stitches to enhance seam elasticity. The edge of composite is made up of two outer and inner layers while the middle layer is sealed in the seam line. The composite is “moulded” into a 3D shape by a fabric-moulding machine. The color of the outer layer is used as a size code.

(3) The fastening system consists of a back band and a top band. The back band is curved to fit on the occipital bone at the back. The top band is in an inverted “Y” shape and is fixed to the right side of the back band.

(4) Two pairs of hook-and-loop tapes are used. The loop side of the tape is fixed to the right side of the back band. One of the hook tapes is sewn on the left side of eye-patch panel and the other is sewn on the end of the top band.

The pattern details are presented in Appendix 5.

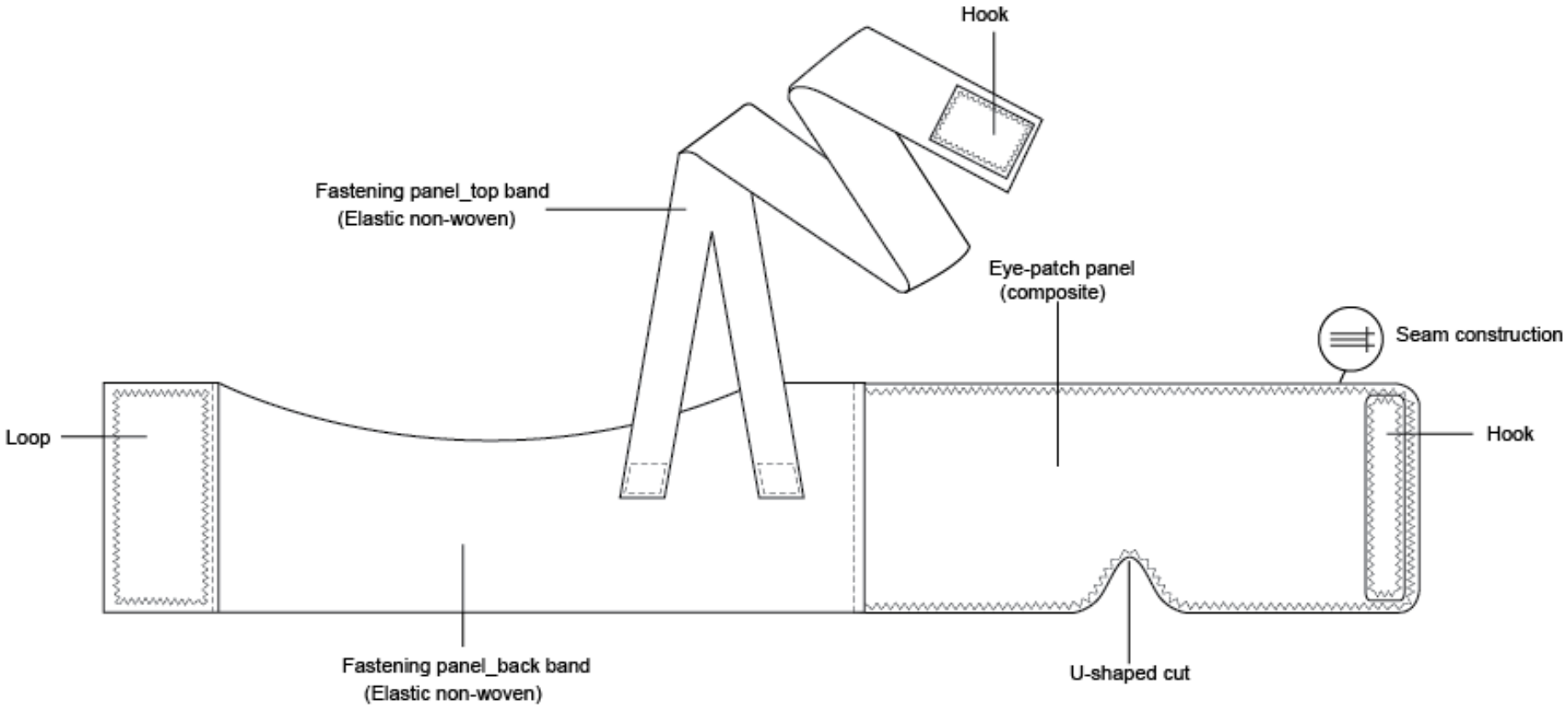


Figure 5-8: Design of Initial EP_n (Style 2)

5.3.1.3 Style 3 of Initial EP_n Design

The design of initial EP_n, Style 3, is presented in Figure 5-9. The design features of Style 3 are shown below:

(1) The eye-patch panel is a 3-layer composite in a rectangular shape with round corners. A U-shape is cut is in the middle. Two pleats are inserted at the U-shape to fit on the protruding ethmoid bone and the shape of the nose. The two pleats are also inserted at the top of eye-patch panel for balancing.

(2) The 3-layer composite is sewn together by stitch 301 and seam 1.16.

(3) A large elastic band panel is used to hold the EP in place securely.

(4) One pair of hook-and-loop tapes is used. The loop tape is fixed to the right side of the back band while the hook tape is sewn on the left side of the eye-patch panel.

The pattern details are presented in Appendix 6.

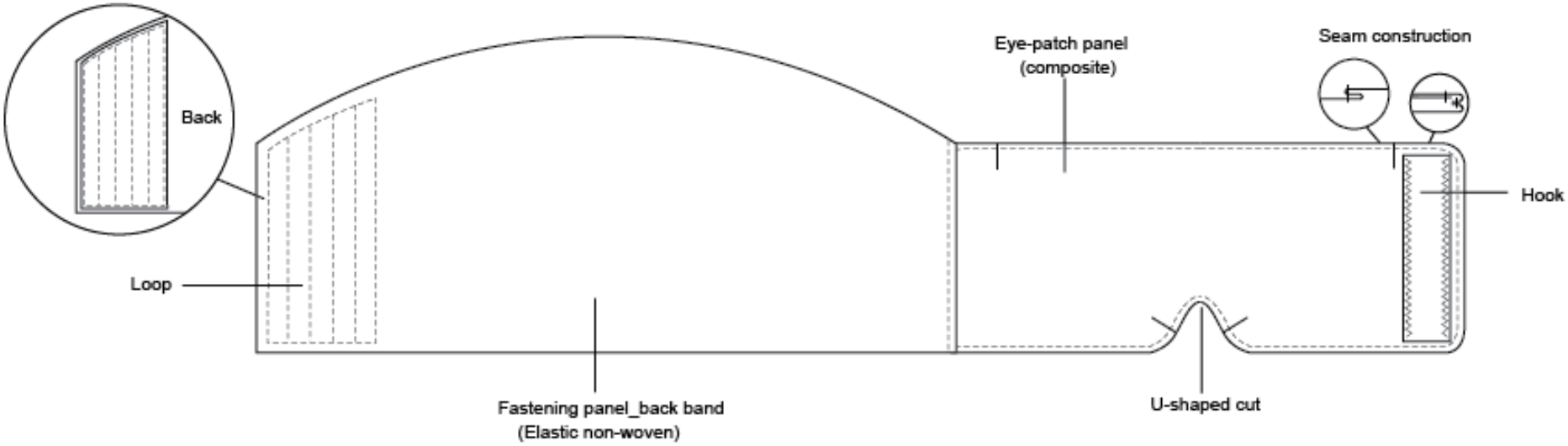


Figure 5-9: Design of Initial EP_n (Style 3)

5.3.1.4 Style 4 of Initial EP_n Design

The design of initial EP_n, Style 4, is presented in Figure 5-10. The design features of Style 4 are shown below:

(1) The eye-patch panel is a 3-layer composite in a rectangular shape. A U-shape is cut in the middle.

(2) The 3-layer composite is sewn together by zigzag stitches to enhance seam elasticity. The edge is pruned in zigzags.

(3) The fastening system is a whole band with its front part covering the eye-patch panel. The front band is in a rectangular shape while the back band is a large elastic panel with a hole. The two sides and the center of eye-patch panel are sewn to the rectangular band.

(4) One pair of hook-and-loop tapes is used. A loop is fixed to the right side of the fastening band while a hook is sewn on the left side of fastening band.

The pattern construction is shown in Appendix 7.

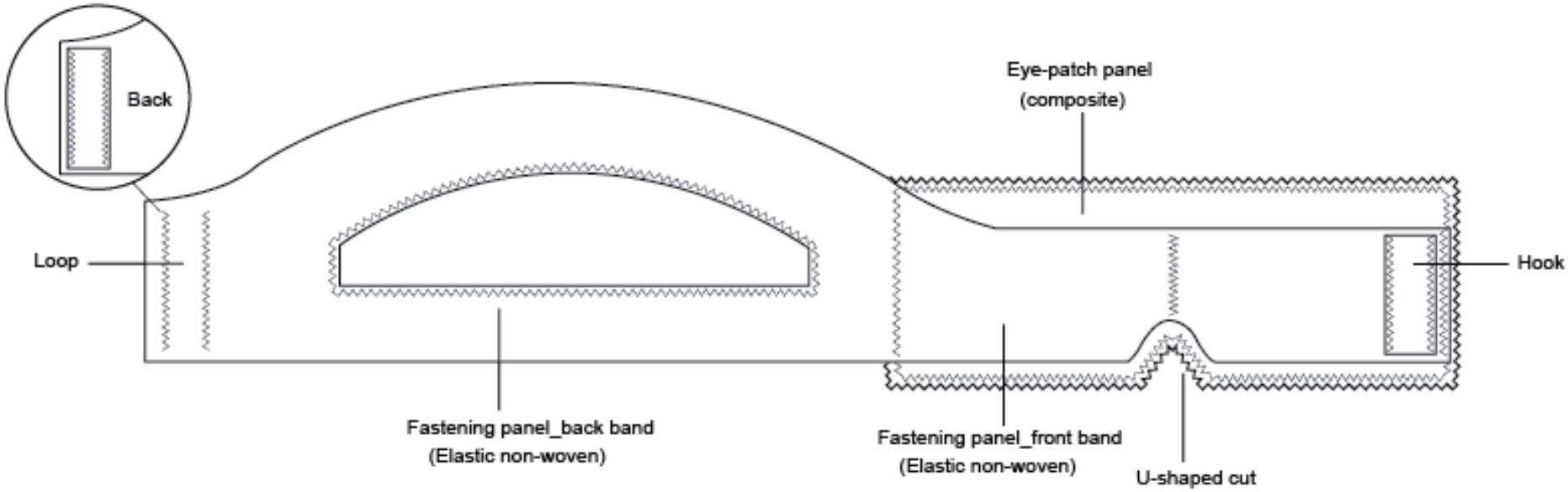


Figure 5-10: Design of Initial EP_n (Style 4)

5.3.2 Production Specifications of the EP_n Prototypes

5.3.2.1 Sizes of the EP_n Prototypes

The research work in Section 4.5 of Chapter 4 reveals that the head circumference of neonates is a key dimension of the sizing system of EPs. Based on the 41 head circumference measured in QMH, two sizes (i.e. small and medium) should be specified for the development of EP_n's sizing system for full-term neonates (see Table 5-25).

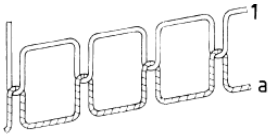
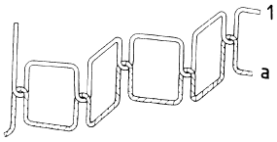
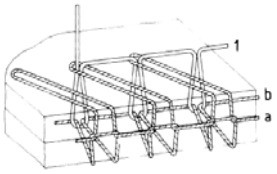
Table 5-25: Sizing system of EP_n for full-term neonates

Sizes	Small (S)	Medium (M)
Neonates' head circumference (mm)	310-349	350-389

5.3.2.2 Stitch Type

Stitches are a unit of conformation from one or more strands/loops intralooping, interloping, passing into or through materials, etc. Based on the provisions of BS 3870-1:1991, three types of stitches were selected for making-up of EP_n: 301, 304 and 504. Their characteristics, parameters, configurations, and applications are presented in Table 5-26.

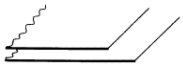
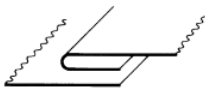
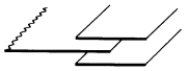
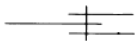
Table 5-26: Stitch types for EP_n prototypes

Stitch type	301	304	504
Characteristics	1) Strong seam with good strength and abrasion 2) Not easy to unravel 3) Comfortable	1) Strong seam, good strength, not easy to unravel 2) Ornamental appearance 3) Good seam elasticity	1) Enclose raw edges or plies
Stitch Parameters	1) Stitch density: 0.5 s/mm	1) Seam width: 2 mm 2) Stitch density: 0.3 mm	1) Seam width: 3 mm 2) Stitch density: 1.1 s/mm
Configurations			
Applications to EP_n prototypes	1) Join eye-patch panel and fastening panel 2) Join three-layer fabrics together as composite for eye-patch panel 3) Fix hook-and-loop tape to EP	1) Join three-layer fabrics together as composite for eye-patch panel 2) Join eye-patch panel and fastening panel	1) Control edges of non-woven fabric in fastening system

5.3.2.3 Seam Type

Seams are the application of a series of stitches to one or several materials (BS3870). The selection of seams depends on the type of fabric, the placement or position of seams, use and care of garments [160]. The wearing comfort is taken into account for EP_n manufacturing. The seam types for the EP_n are presented in Table 5-27.

Table 5-27: Seam types for EP_n prototypes

Seam type	Characteristics	Material configurations	Location of needle	Applications
1.02	1) Seam on folded edge to reduce thickness 2) Smooth surface of wide-piece material 3) Good strength			1) Seam for joining three-layer fabrics 2) Seam for joining hook or loop and non-woven fabric or composite
1.16	1) Smooth edge 2) Good strength			1) Seam for joining three-layer fabric
2.02	1) Good strength 2) Seam thickness reducing with folded edge of one-piece material to smooth the edge 3) Good appearance			1) Seam for joining eye-patch panel and fastening system
5.02	1) Shape construction			1) Seam for pleat on eye-patch panel
5.03	1) Shape construction			2) Seam for pleat on eye-patch panel
5.53	1) Seam on folded edge to reduce thickness			1) Seam for joining three-layer fabric

5.3.2.4 Machines Used

In this research, the direct-drive lockstitching machine was used for fixing different fabric pieces. A zigzag stitching machine was used for joining three single-layer fabrics as a composite and an overlock stitching machine was used for folding edges of non-woven elastic fabrics. The details of the sewing machines are presented in Table 5-28.

Table 5-28: Sewing machine used in the manufacturing of EP_n

Sewing Machine	Brother® S-7200A single–needle, direct-drive, straight lockstitcher with thread trimmer	Juki® LZ-2290a-SS computer-controlled, direct-drive, high-speed, 1-needle, lockstitching, zigzag stitching machine	Pegasus® EX5205-12 overlock stitching machine
Parameters	1) Max speed: 5000 rpm	1) Max speed: 5000rpm 2) Max zigzag width: 10 mm	1) Speed: 2860 rpm
Related stitch	301	304	504

In addition to the sewing machines, the Optotex Form Moulding Machine Type 3032 was also used for Style 2. The 3-layer composite was moulded at 170°C and 70 second to create a 3D shape.

5.3.2.5 Sewing Thread

There are many kinds of sewing threads. Cotton, silk, nylon, polyester, and cotton-wrapped polyester threads are generally used in the manufacture of clothing. For EPs, the properties of fabric, including fiber content, structure, weight, elasticity, color, EP usage, types of sewing machines, parameters of stitches and seams, and quality and cost of thread, are taken into account for sewing thread selection.

COATS astra® white 100% staple spun polyester thread with 18tex was selected for the manufacture of EP_n. It is manufactured by Coats China Company. Firstly, the polyester thread is suitable for most fabrics, particularly woven, knitted, and stretch fabrics of any fiber. It is commonly used for children's apparel and matches stretch

composites and elastic bands [64]. Secondly, thread fineness of 18tex matches the composite, especially the knitted outer-layer fabric. Thirdly, its smooth surface, low linting and non-toxic chemical lubricants can avoid irritation to the neonate's soft and delicate skin. Fourthly, its good strength can meet the requirements for high-speed sewing operation. Finally, its low cost conforms to the EP's disposability.

5.3.2.6 Needle Type and Size

The needle is very important for EP manufacturing. Its parameters are types and sizes. The needle types include sharp point (regular), ball point, and wedge point. Its selection depends on fabric structure. As the materials of EP_n are woven, knitted and non-woven fabrics, the sharp-point needle was chosen because it produces even stitches and minimizes fabric puckering. In addition to choosing the right type of needle, the needle size is also important. Regular point needles come in a wide range of sizes, from a fine size 9 to a heavy size 18. The needle size was selected for its compatibility with fiber content, the type and size of fabric yarn, the structure and weight of fabric, the length and formation of stitch, etc. [160]. Generally, the thinner the material is, the finer the needle is used. A fine-size needle can avoid materials being pushed into the hole of a throat plate and being damaged [62]. The yarns of the inner and outer layers of the composite are fine (14.5 tex and 18.0 tex respectively) while non-woven fabrics also need fine needles. Therefore, a size 9 Organ needle was chosen.

5.3.3 Comments on Initial EP_n Designs

Four initial EP_n prototypes were reviewed by the medical staff in the SCBU of QMH. During the interviews, the four EP_n prototypes were put onto a plaster model of the neonate's head. The comments by the medical staff were recorded and analyzed. The details are summarized in Tables 5-29.

Table 5-29: Comments on initial developed prototypes of EPs by medical staff

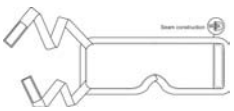
Prototypes of EP_n	Positive comments	Negative comments
Style 1 	**Eye-patch panel** 1) Good shape and fitting; avoiding suffocation 2) Round corner safe for neonate's soft skin 3) "Ease" minimizing light gaps and reducing pressure on eyes	**Eye-patch panel** 1) Very rough binding 2) Complex design possibly incurring high costs
	Fastening panel 1) Easy to handle 2) Simple design and low cost	**Fastening panel** 1) Potential risk of wrapping around neonate's neck 2) Difficult to keep top band in place
Style 2 	**Eye-patch panel** 1) Good shape, fitting, and safe design 2) Zigzag stitches more comfortable than binding 3) Moulded 3D shape reducing pressure on eyes 4) Good colour code for size identification	**Eye-patch panel** 1) Nose part of eye-patch panel possibly causing light gaps
	Fastening panel 1) Back band reducing contact and rubbing against cot/pillow 2) Top band holding eye-patch panel in optimum position 3) Easy to handle	**Fastening panel** 1) Overlapping thickness of two panels causing discomfort 2) Location of loop causing displacement of top band 3) Hook side of top band possibly causing skin irritation

Table 5-29: Comments on initial developed prototypes of EPs by medical staff (continued)

Prototypes of EP_n	Positive comments	Negative comments
Style 3 	**Eye-patch panel** 1) Good shape and fitting; avoiding suffocation 2) Round corner safe for neonate's soft skin 3) 3D shape generated by pleats minimizing light gaps and reducing pressure on eyes	**Eye-patch panel** 1) Pleat and stitiches possibly causing skin irritation 2) Very thick composite edge
	Fastening panel 1) Simple and easy to handle	**Fastening panel** 1) Potential EP displacement 2) Overlapping thickness of two panels causing discomfort
Style 4 	**Eye-patch panel** 1) Elastic non-woven fabric minimizing light gaps	**Eye-patch panel** 1) Spiculate edge dangerous for neonate's eye and skin 2) Causing bruises and high pressure on eyes potentially 3) Unfavorable appearance
	Fastening panel 1) Fastening panel easy to handle	**Fastening panel** 1) Overlapping thickness of two panels causing discomfort 2) Complex production operations 3) Difficult to match fastening band with head morphology

As shown above, the major concerns of EP_n lie in photo-protection, safety, security, easy handling, skin irritation, comfort, appearance, and production.

5.4 Modifications of EP_n Design ($EP_{n.v1}$) for the First Wear Trial in Hospital

In view of the comments given above, the design features with positive comments were assembled and a new prototype was generated as follows.

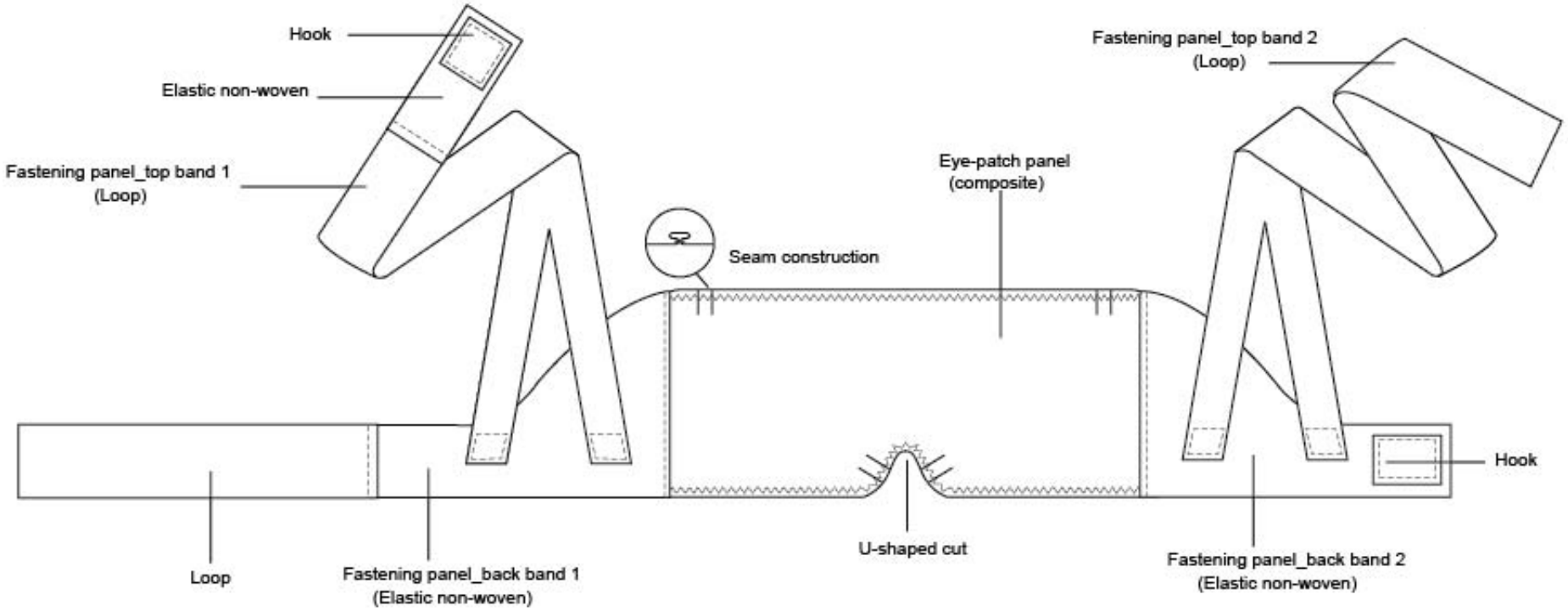


Figure 5-11: The design of modified EP_n ($EP_{n.v1}$) for first wear trial

The design of the modified EP_n ($EP_{n.v1}$) is presented in Figure 5-11. The design features are discussed below:

(1) The eye-patch panel is a 3-layer composite in a rectangular shape with round corners. A U-shape is cut in the middle to accommodate the shape of the nose. The 3D shape of the eye-patch panel is generated by two pleats inserted in the U-shaped cut and the two pleats are inserted in the top of the eye-patch panel.

(2) The 3-layer fabrics are sewn together by zigzag stitches. The edge of the composite consists of two outer/inner layers while the middle layer is sealed in a seam line. The colors of the outer layer are used as a size code and improve the appearance.

(3) The fastening system consists of two back bands and two top bands. The back right band consists of two segments: a non-woven fabric fixed to the eye-patch panel and a loop with a free end. The back left band fixed to the eye-patch panel is non-woven fabric with a hook fixed to its end. They are joined at the back of the head.

(4) The top right band consists of two segments: a loop fixed to the ear location of the back band and a non-woven fabric with a free end. While a hook is fixed to a free end, the top left band is a loop fixed to the ear location of the back band. The two top bands are joined at the top of head.

Characteristics of $EP_{n.v1}$ include:

(1) The rectangular shape offers a large eye-covering area with safe restrictions compared with current EPs. The round corner is safe for the neonate's tender skin. The U-shaped cut with pleats not only minimizes the light gaps but also reduces the level of pressure on the neonate's eye. The seam widened from 5.02 to

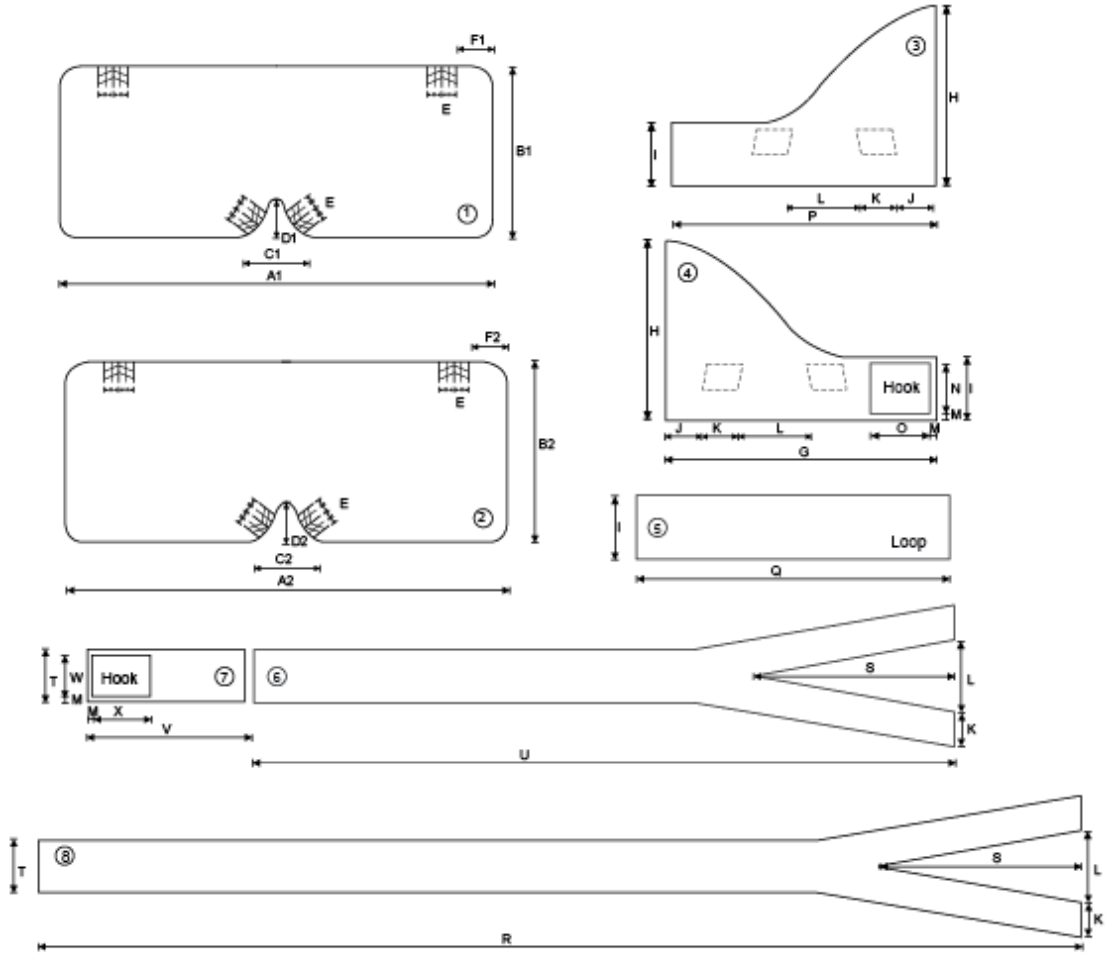
5.03 provides a plain pleat with added comfort.

(2) The zigzag stitches not only maintain the extensibility of the composite but also reduce eyelid bruises and irritation by soft-knitted free-end edges.

(3) The back bands keep the eye-patch panel on the neonate's head directly. The concave shape formed by the two back bands avoids the occipital region and therefore minimizes contact and rubbing of the EP against the cot/pillow. The widened width of the back band covers the whole ear and therefore minimizes discomfort of the ear. The top bands joined at the ear location keep the back band in place.

(4) The loop ends of the top/back bands of the EP's fastening system can be adjusted according to the neonate's shape.

The pattern of the $EP_{n.v1}$ for the first wear trial is presented in Figure 5-12 and its dimensions are shown in Table 5-30.



① Eye-patch panel-Middle layer (Woven fabric)
② Eye Patch panel_Inner/outer layer (Knitted fabric)
③ Fastening panel_Back band 1 (Elastic non-woven fabric)
④ Fastening panel_Back band 2 (Elastic non-woven fabric)
⑤ Fastening panel_Back band 1 (Loop)
⑥ Fastening panel_Top band 1 (Loop)
⑦ Fastening panel_Back band 1 (Elastic non-woven fabric)
⑧ Fastening panel_Top band 2 (Loop)

Figure 5-12: Pattern construction of modified EP_n ($EP_{n.v1}$) for the first wear trial

Table 5-30: Pattern dimensions of $EP_{n.v1}$ in small and medium sizes

Small Size (mm)	Medium Size (mm)
As1 = P1+1/2*(1/2*M1-P1)+5 = 120	Al1 = P1+1/2*(1/2*M1-P1)+5 = 132
As2 = Am1+5 = 125	Al2 = A21+5 = 137
Bs1 = (1/2*P3+10)+(P9+8) = 50	Bl1 = (1/2*P3+10)+(P9+8) = 51
Bs2 = B11+5 = 55	Bl2 = B11+5 = 56
Cs1= P6+7 = 20	Cl1 = P6+10 = 23
Cs2 = C21 = 20	Cl2 = C21 = 23
Ds1 = 1/2*(P9+8)+3 = 18	Dl1 = 1/2*(P9+8)+5 = 20
Ds2 = Ds1 = 18	Dl2 = Dl1 = 20
Es1 = 4	El1 = 4
Fs1 = 20	Fl2 = 20
Gs = 3/4*1/2*(M1- As2) = 77	Gl = 3/4*1/2*(M1- Al2) = 86
Hs = Bs2-2 = 53	Hl = Bl2-2 = 54
Is = 2/5* Bs2 = 22	Il = 2/5* Bl2 = 22
Js = 3/4*1/2*(M2-As2) = 15	Jl = 3/4*1/2*(M2-Al2) = 15
Ks = 13	Kl = 13
Ls = 15	Ll = 15
Ms = 1	Ml = 1
Ns = 20	Nl = 20
Os = 22	Ol = 22
Ps = Ds1-10 = 67	Pl = Dl1-10 = 76
Qs = 110	Ql = 110
Rs = 165	Rl = 164
Ss = 50	Sl = 50
Ts = 15	Tl = 15
Us = 95	Ul = 95
Vs = 50	Vl = 50
Ws = 20	Wl = 20
Xs = 22	Xl = 22

5.5 Conclusions

In this chapter, the fabrication and initial designs of the EP_n are discussed and evaluated. Based on the physical functional requirements, physiological and psychological comfort requirements, and practical use of the EP used in the neonatal unit, a three-layer composite for the eye-patch panel was determined. It consists of a

cotton/Modal® blended knitted inner layer,, a cotton woven middle layer and a cotton knitted outer layer. A polyethylene/polypropylene non-woven band-type elastic material and a nylon loop-and-hook tape constitute the fastening system. Four initial EP prototypes were developed and reviewed by the medial staff at QMH. An EP prototype ($EP_{n.v1}$) is designed based on the modification of the four initial EPs. In the next chapter, the first wear trial in the hospital is carried out to evaluate the practical use and performance of the modified EP design.

CHAPTER 6: WEAR TRIAL IN HOSPITAL AND MODIFICATIONS OF EPS

6.1 Introduction

This chapter presents Stage 5 of the protective product development process – evaluation of end-uses. Two wear trials of the EP_n prototype were conducted in the hospital to evaluate its end-uses in terms of fitting, comfort, security, safety, easy handling, and appearance. Based on the results of the first wear trial, some design modifications were made. The modified EP_n design was then further examined in the second wear trial. The overall workflow of the Protective Product Development Process is presented in Figure 6-1.

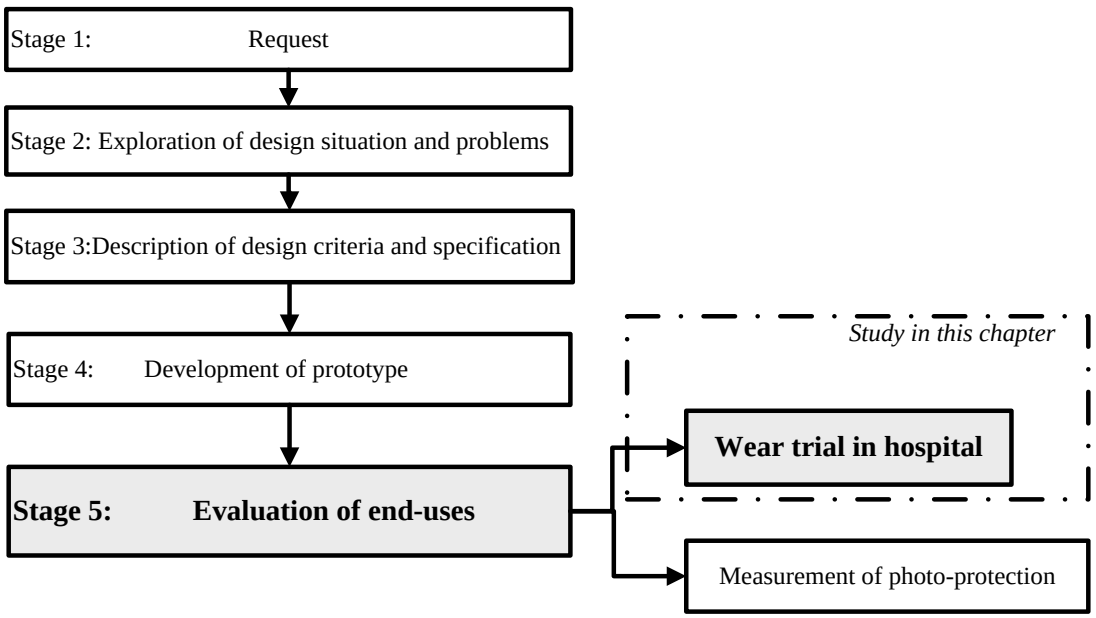


Figure 6-1: Stage 5 of the protective product development process

6.2 First Wear Trial for $EP_{n.v1}$ in Hospital

6.2.1 Participated Neonates

With the consent of the parents or guardians, a total of 10 full-term neonates were invited for the first wear trial of the $EP_{n.v1}$. A summary of their age and body dimensions is presented in Table 6-1. The details are presented in Appendix 8. All participants were aged below 15 days. Neonatal jaundice is commonly found in neonates in their first week of life and EPs are used for phototherapy treatment. As a precaution to minimize risks, the first wear trial was conducted in the SCBU of QMH without phototherapy light.

Table 6-1: A summary of subjects participating in the first wear trial

Number of subjects	Age (day)			Head circumference (mm)			Size of $EP_{n.v1}$
	Range	$\bar{x}$	s	Range	$\bar{x}$	s	
7	6.0	3.3	2.4	28.0	330.9	9.8	Small
3	6.0	3.0	3.5	10.0	355.0	5.0	Medium

6.2.2 Procedure for the First Wear Trial

The procedures for the first wear trial of the EP prototype are shown below:

Stage 1: A subject was prepared in an incubator or cot. The newly developed EP ($EP_{n.v1}$) in an appropriate size was selected according to its head circumference.

Stage 2: The EP was put onto the neonate's head by the medical staff;

Stage 3: The wear trial lasted for 180 minutes with two feeding intervals. During the wear trial, each neonate was observed and evaluated by one or two medical staff

members to ensure early detection of adverse events. The EP would be removed immediately when discomfort or potential hazard was caused by the procedure.

Stage 4: After the wear trial, the EP was taken off and disposed of by the medical staff.

6.2.3 Evaluation of $EP_{n.v1}$ in the First Wear Trial

In order to evaluate the effectiveness and performance of the newly developed EP prototype, a questionnaire was designed and distributed to the medical staff and caregivers in the SCBU. $EP_{n.v1}$ was evaluated in terms of 1) sizing, fitting and security, 2) design and material comfort, 3) safety, 4) easy handling and 5) appearance. The questionnaire adopted a 5-point scale. The score assignment and denotation for each scale were designed as: 5-Extremely acceptable, 4-Acceptable, 3-Neutral, 2-Unacceptable, and 1-Extremely unacceptable. Based on the wear trials for the 10 neonates, a total of 15 questionnaires were collected.

A summary of the results is presented in Figure 6-2, and an error bar plot presenting the mean and standard deviation for each evaluated item is shown in Figure 6-3.

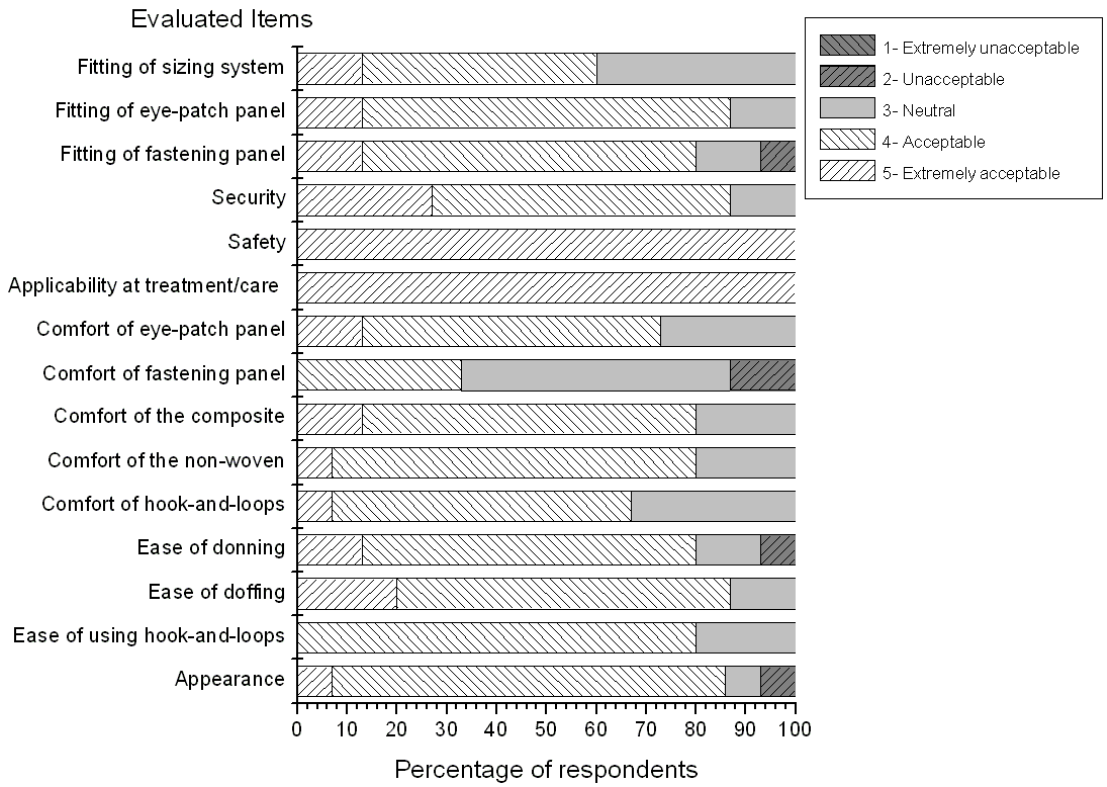


Figure 6-2: Questionnaire survey results in the first wear trial ($EP_{n.v1}$)

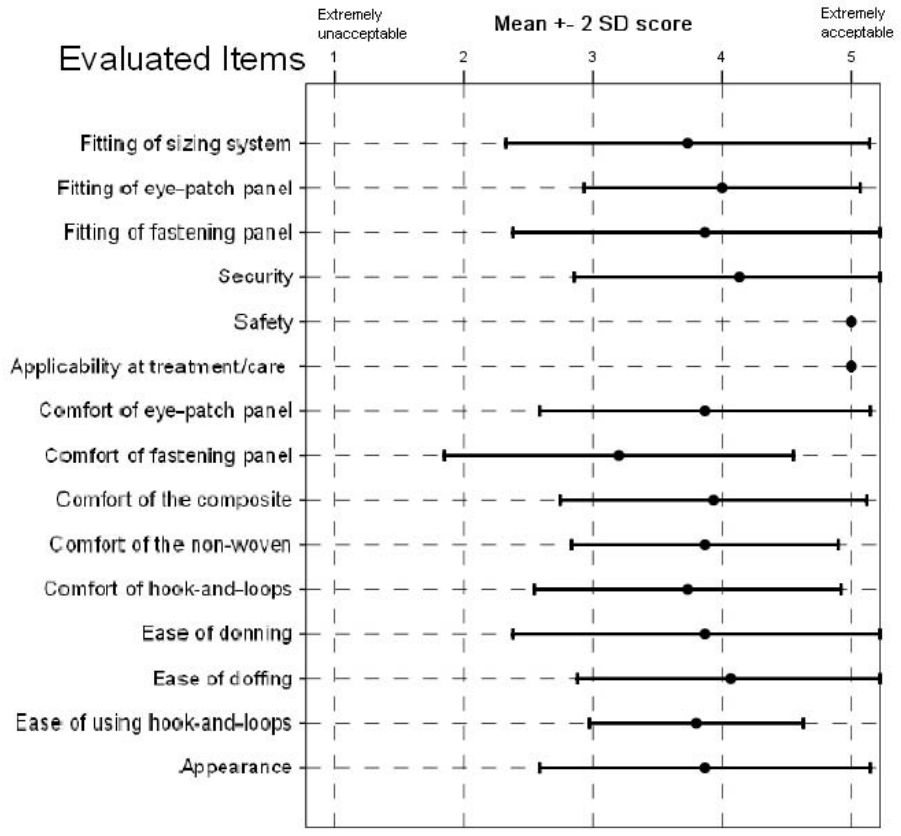


Figure 6-3: The error bar plot of the survey results in the first wear trial ($EP_{n.v1}$)

According to the results, two of the size specifications (small and medium sizes) of the $EP_{n.v1}$ are well perceived by the respondents (a mean score of 3.73). Regarding the sizing, most of the respondents agreed that the fitting of $EP_{n.v1}$ is good (with mean scores of 4.00 for the eye-patch panel and 3.87 for the fastening panel). Nevertheless, one of the respondents did not accept the fitting of the back band. The respondent further explained that there is a little gap at the foot of the top band, which may catch the little fingers of the neonates and the $EP_{n.v1}$ may be pulled away easily.

As neonates move from time to time due to invasive medical treatment and/or physiological needs, it is a persistent problem that the eye-patches are displaced very quickly, allowing light to go directly into the neonate's eyes. The security/displacement of EP_n is a very important parameter for its end-use evaluation. Most of the respondents agreed that $EP_{n.v1}$ can be held in an optimum position effectively during the 180 minutes wear trial, especially some of the neonates cried and moved vigorously during the wear trial. The mean rating score was remarkably high (4.13).

All respondents fully agreed that $EP_{n.v1}$ design is safe. No adverse event, hazards or discomfort was observed during the wear trial.

All of the respondents fully agreed that $EP_{n.v1}$ design does not cause any extra difficulty to routine medical treatment and/or care. No adverse event or inconvenience was observed during the wear trial.

Most respondents agreed that the eye-patch panel is comfortable (with a mean score of 3.87). Nevertheless, the score of the fastening panel's comfortability was the

lowest among the 15 evaluated items (with a mean score of 3.20). Two of the respondents disapproved of the fastening panel. They explained that the opening design at the anterior frontanelle of the skull may cause pressure and discomfort at binding. It is evident that most of the respondents accept the comfortablity of the composite, the elastic non-woven fabric and the hook-and-loop fasteners (with mean scores of 3.93, 3.87 and 3.73 respectively).

In view of the intensive medical treatment/care in the hospital, the handling performance of EPs becomes an important factor in affecting its daily use. The results show that most of the respondents approve of the easy handling of $EP_{n.v1}$ in terms of donning, doffing and using hook-and-loops (with mean scores of 3.87, 4.07 and 3.80 respectively). However, one respondent remarked that it is difficult to bind the two top bands at an appropriate pressure level.

All the respondents but one were satisfied with the appearance of $EP_{n.v1}$ (with a mean score of 3.80). The appearance of $EP_{n.v1}$ was commented as lack of integrality.

In summary, positive comments were generally obtained on the newly developed $EP_{n.v1}$ in terms of fitting of the front panel, fitting of the sizing system in two EP sizes, comfort of the eye-patch panel design, comfort of materials, security, safety, ease of doffing, ease of using hook-and-loops, applicability to medical treatment and care, etc. However, some further modifications are needed in aspects like fitting of the fastening panel, comfort of the fastening panel, ease of donning, and appearance.

6.3 Modifications of $EP_{n.v1}$

6.3.1 Design Modifications

The evaluated results of $EP_{n.v1}$ demonstrate that the design of the sizing system and the comfort of materials are acceptable while the problems mainly lie in the style design. Therefore, the following modifications were made and highlighted in Figure 6-4.

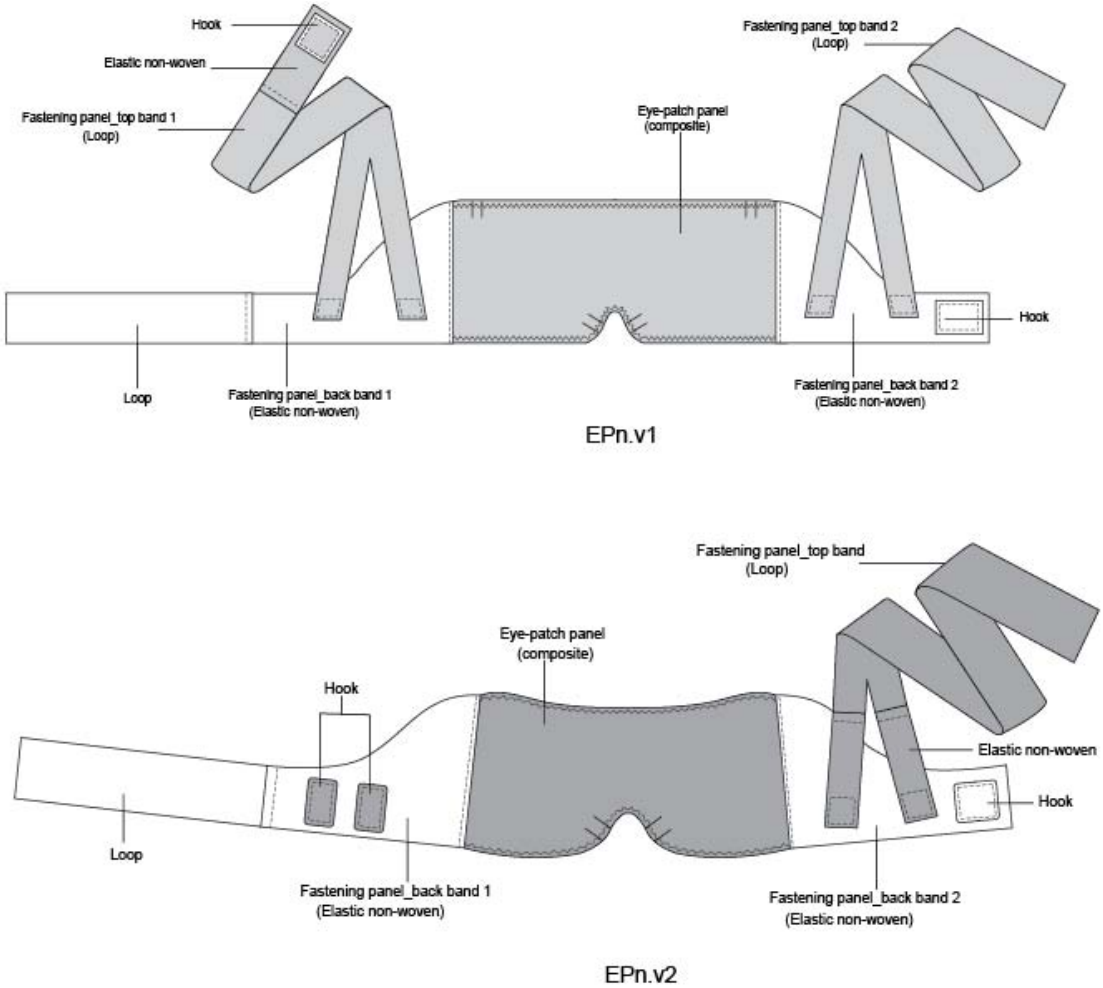


Figure 6-4: Modifications of EP_n (from $EP_{n.v1}$ to $EP_{n.v2}$)

(1) Modification 1: To improve the fitting and comfort of the back panel and

avoid the neonate's fingers being caught, the material of the Y-shaped end of the top band was changed to an elastic non-woven fabric. The elasticity of this material makes the top band able to fit different types of morphology of the neonate's head. It is believed that the elastic band can also relieve the pressure on the head.

(2) Modification 2: To improve the handling and appearance of $EP_{n.v1}$, the opening of the top band was moved to the right side of the back band. As the neonates always lie in the incubator or warm bed when they are treated by phototherapy, it is convenient for caregivers to observe and operate the top band on one side of the back band. The appearance of EPs is accessible by the concision of one top band.

(3) Modification 3: To enhance the design appearance, the two pleats at the top of the front panel were removed. Only two small pleats were added to the bottom near the nose area (the transformation of pleats is shown in Figure 6-6). It is believed that the new design not only enhances the fitting of the nose and top parts of the EP (in different shapes and sizes) and minimizes the light gaps, but also relieves the pressure on the neonate's eyes. For traditional EPs, tight binding causes bruises around the neonates' eyes, compression to the cornea and eyeballs, impairment of drainage of tears, and even infection.

Therefore, Version 2 of EP_n ($EP_{n.v2}$) was generated and shown in Figure 6-5.

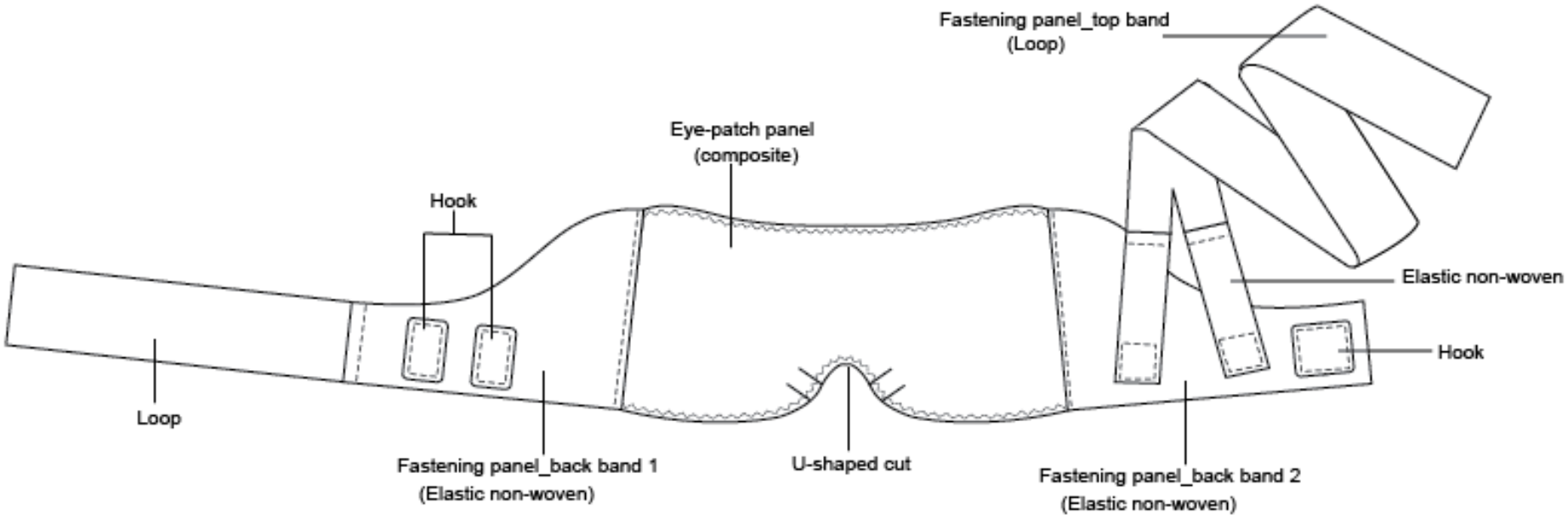
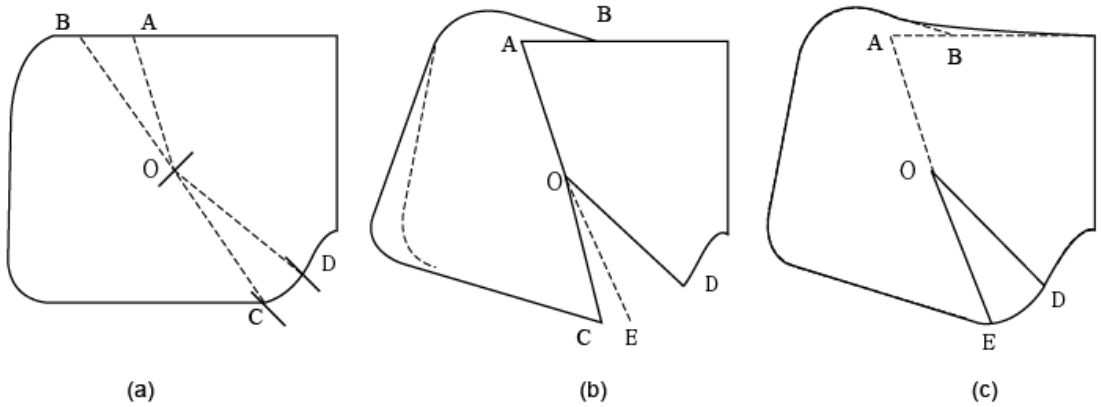


Figure 6-5: Version 2 of EP_n ($EP_{n.v2}$)



(a) Mark the original pleats (OA and OB for the top pleat; OC and OD for the bottom pleat), cut along OC and OD， and then remove OCD.

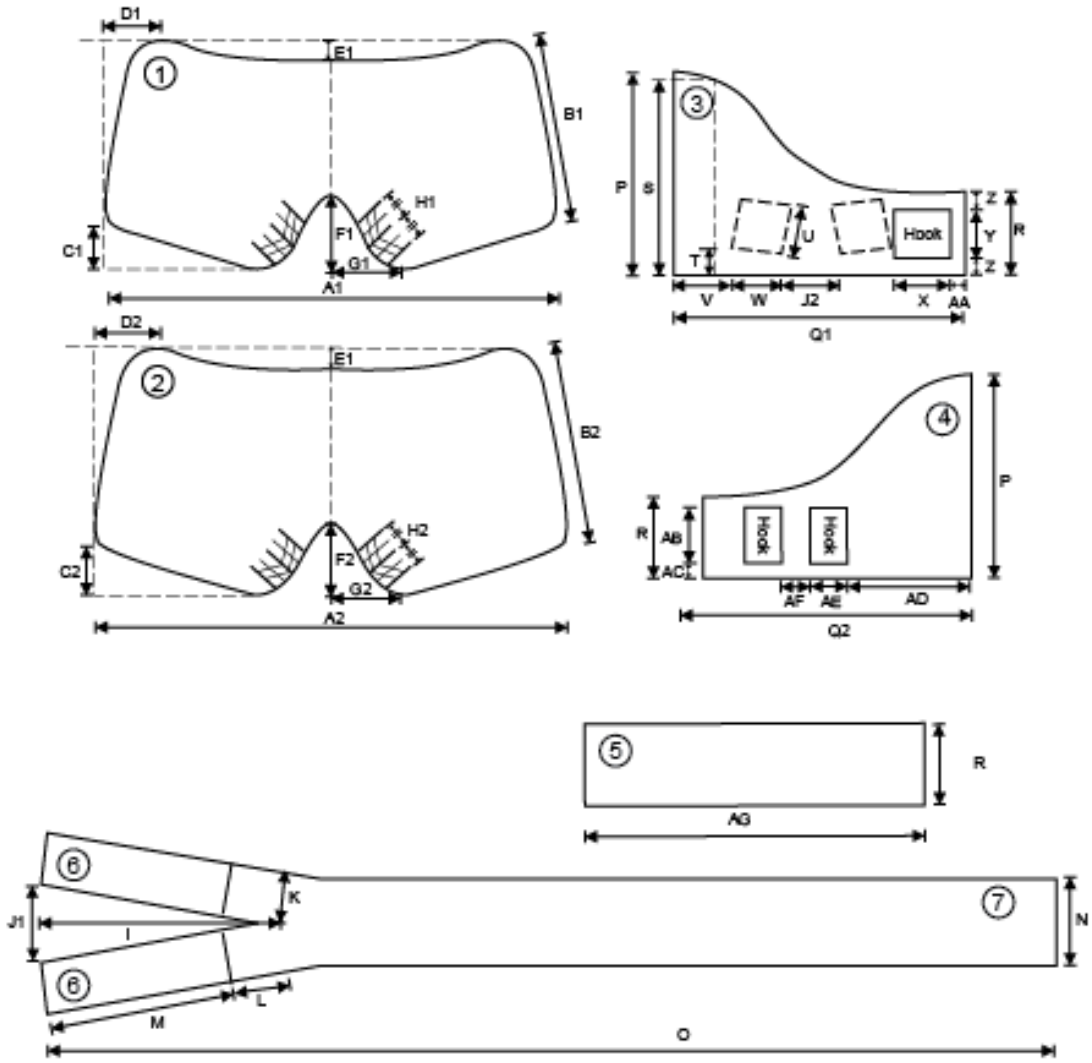
(b) Create a pivot pattern so that OB meets OA. Narrow the pleat width from OC to OE and trim the narrowed dart width on the side of the pattern.

(c) Redraw the outline smoothly

Figure 6-6: Pleats moved to bottom (improving the fitting of nose and top edge)

6.3.2 Pattern Construction

Based on the modification of style design and material application above, the pattern construction in small and medium sizes was established and is presented in Figure 6-7. The related dimensions are shown in Table 6-2.



① Eye-patch panel-Middle layer (Woven fabric)
② Eye-patch panel_Inner/outer layer (Knitted fabric)
③ Fastening panel_Back band 1 (Elastic non-woven fabric)
④ Fastening panel_Back band 2 (Elastic non-woven fabric)
⑤ Fastening panel_Back band 1 (Loop)
⑥ Fastening panel_Top band (Loop)
⑦ Fastening panel_Top band (Elastic non-woven fabric)

Figure 6-7: Pattern construction of modified EP_n ($EP_{n.v2}$)

Table 6-2: Pattern dimensions of the modified EP_n ($EP_{n.v2}$)

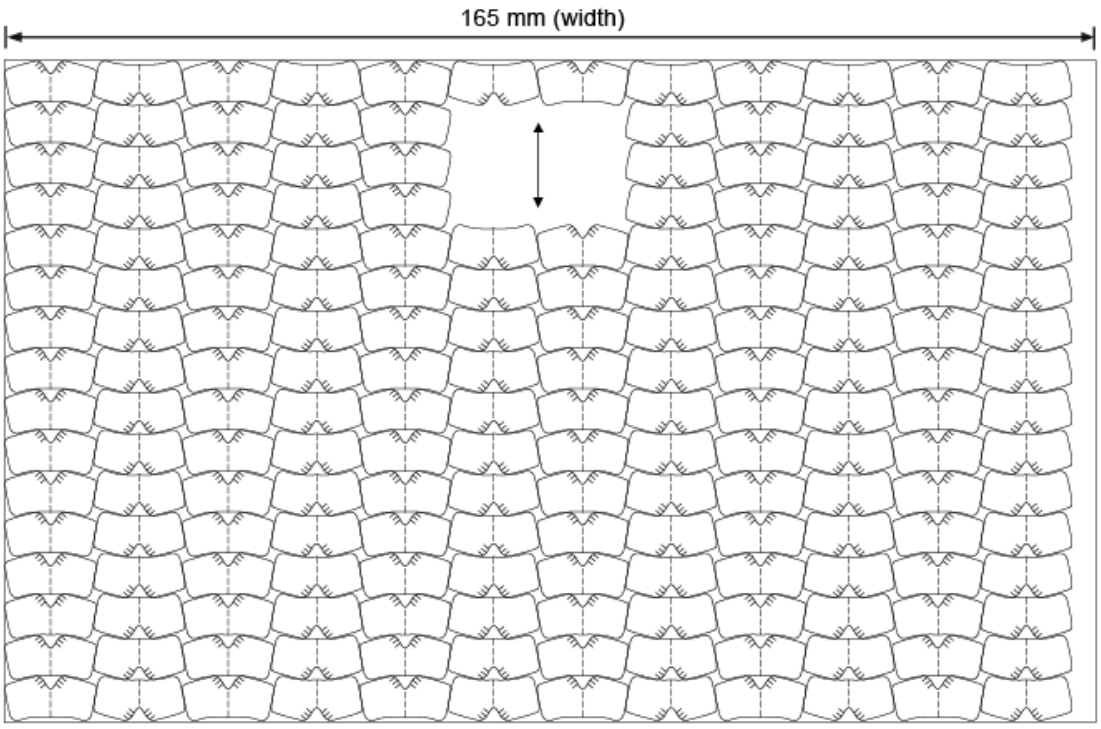
Small Size (mm)	Medium Size (mm)
A1 = P1+1/2*(1/2*M2-P1)+5 = 120	A1 = P1+1/2*(1/2*M2-P1)+5 = 132
A2 = A1+5 = 125	A2 = A1+5 = 137
B1 = (1/2*P3+10)+(P9+8) = 50	B1 = (1/2*P3+10)+(P9+8) = 51
B2 = B1+5 = 55	B2 = B1+5 = 56
C1 = C2 = 13	C1 = C2 = 13.5
D1 = 15	D1 = 18
D2 = D1+3 = 18	D2 = D1+3 = 21
E1 = E2 = 6	E1 = E2 = 6
F1 = F2 = 1/2*(P9+8)+3 = 18	F1 = F2 = 1/2*(P9+8)+5 = 20
G1 = G2 = P6+7 = 20	G1 = G2 = P6+10.5 = 23
H1 = H2 = 6	H1 = H2 = 6
I = 60	I = 60
J1 = 15	J1 = 15
J2 = 3/4*J1=11	J2 = 3/4*J1 = 11
K = 13	K = 13
L = 1/4* $\sqrt{I^2+(J1/2)^2}$ = 15	L = 1/4* $\sqrt{I^2+(J1/2)^2}$ = 15
M = 3/4*I = 45	M = 3/4*I = 45
N = 22	N = 22
O = 5*I = 300	O = 5*I = 300
P = B1-2 = 53	P = B2-2 = 54
Q1 = 3/4*1/2*(M2-A2) = 77	Q1 = 3/4*1/2* (M2-A2) = 86
Q2 = Q1-10 = 67	Q2 = Q1-10 = 76
R = 2/5*B2 = 22	R = 2/5*B2 = 22
S = P12+27 = 50	S = P12+27 = 53
T = 8	T = 8
U = 13	U = 13
V = 3/4*1/2*(M3-A2)+7 = 22	V = 3/4*1/2*(M3-A2)+7 = 22
W = 14	W = 14
X = 15	X = 15
Y = 13	Y = 13
Z = 4.5	Z = 4.5
AA = 3	AA = 3
AB = 15	AB = 15
AC = 4	AC = 4
AD = 25	AD = 25
AE = 10	AE = 10
AF = 3/4*AE = 8	AF = 3/4*AE = 8
AG = 110	AG = 110

6.3.3 Marker Plans for Materials and Calculation of Cost

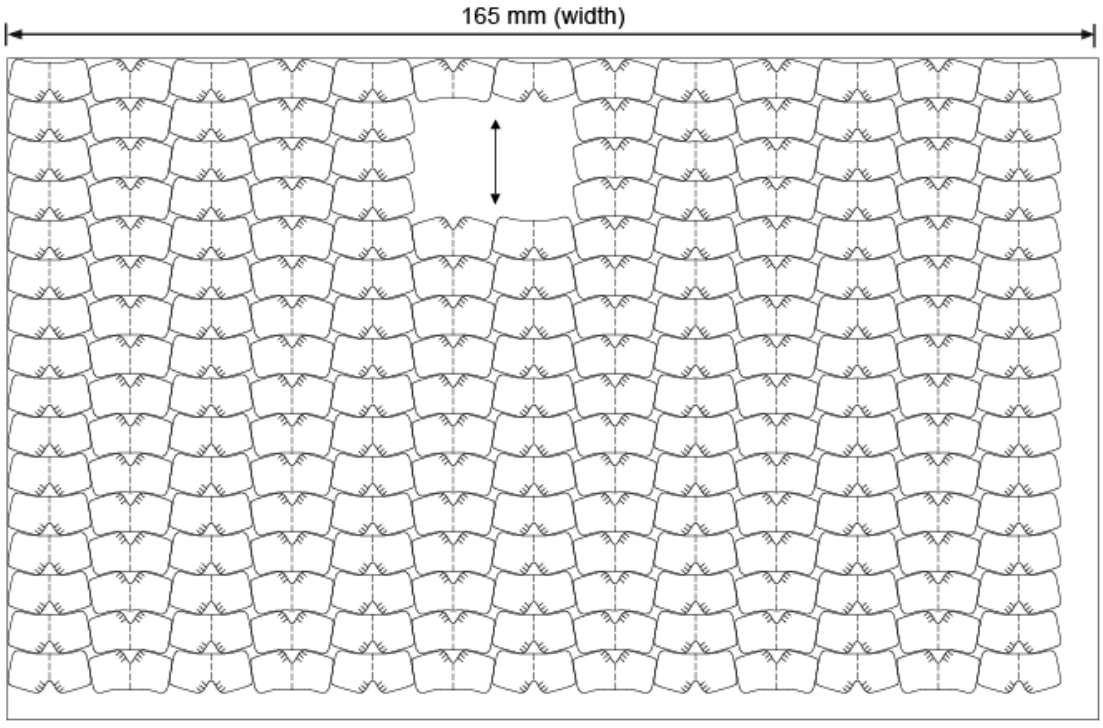
6.3.3.1 Marker Plans for Materials

Marker plans for materials were conducted by arranging the pattern pieces on selected fabric materials economically. Based on these marker plans, the cost of materials was calculated.

The marker plan for the composite's knitted inner-layer fabric, woven middle-layer fabric, knitted outer-layer fabric, the non-woven fabric for the fastening panel, and the hook-and-loops are presented in Figures 6-8, 6-9, 6-10, 6-11, 6-12, and 6-13. The width of the material is marked and the length is 100 mm in each figure. According to the style design, the marker plans for the composite's inner layer, middle layer, outer layer, and the non-woven fabric for the fastening panel are arranged for the pattern pieces in small and medium sizes while the marker plans for hook-and-loops are arranged in one size as the patterns of hook-and-loop materials are the same in small and medium sizes.

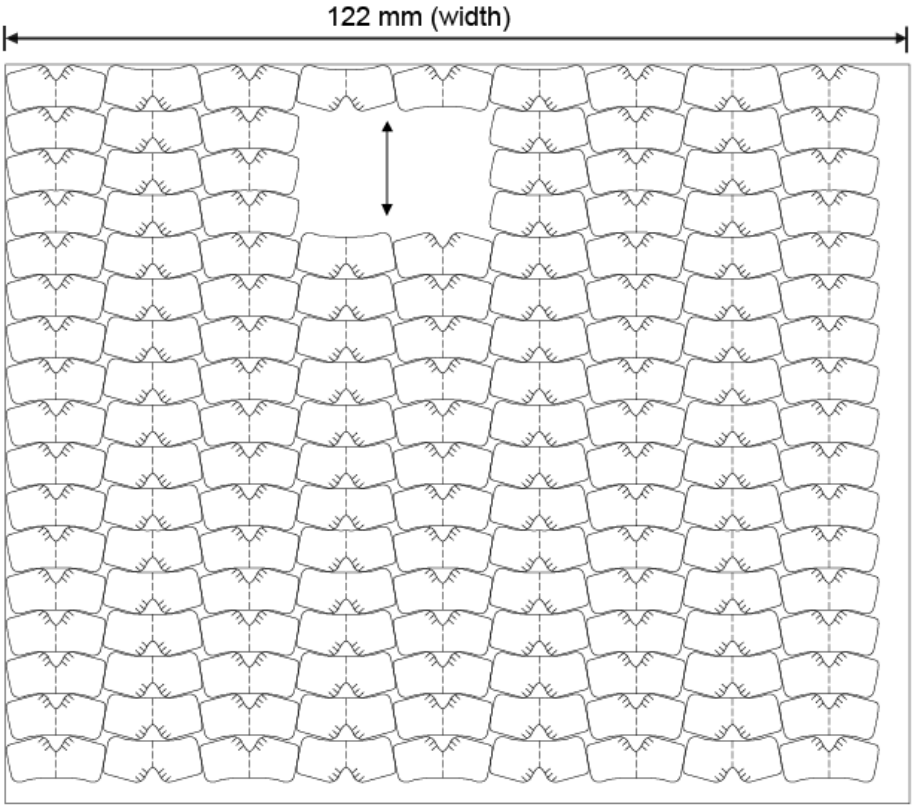


(a) Medium size

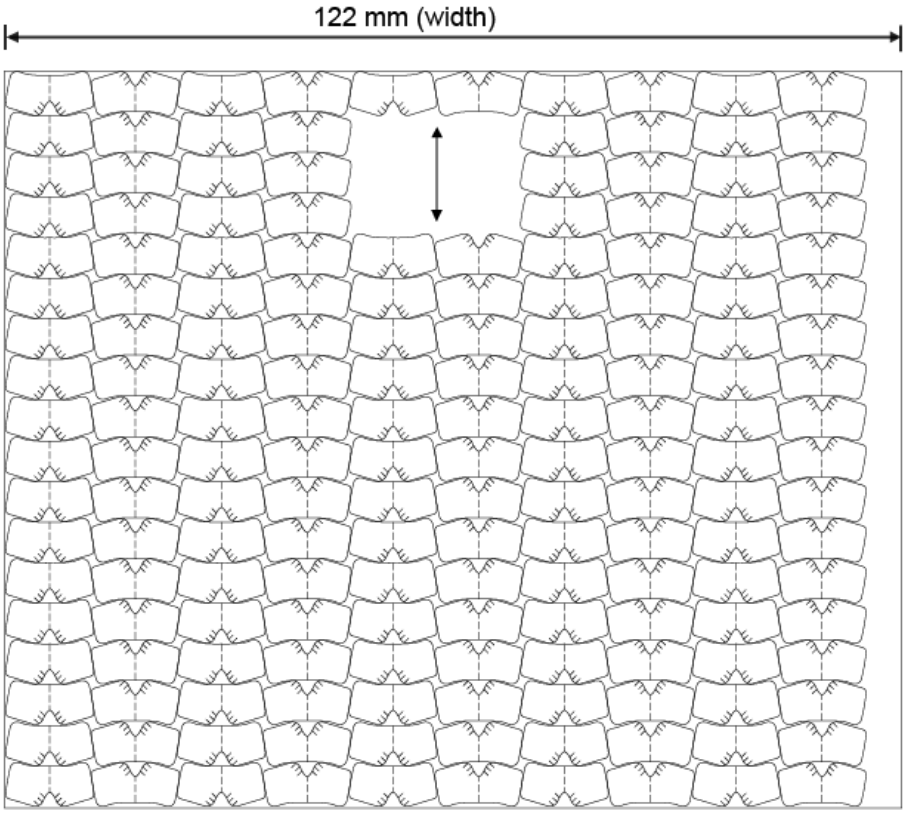


(b) Small size

Figure 6-8: The marker plan for inner-layer knitted fabric

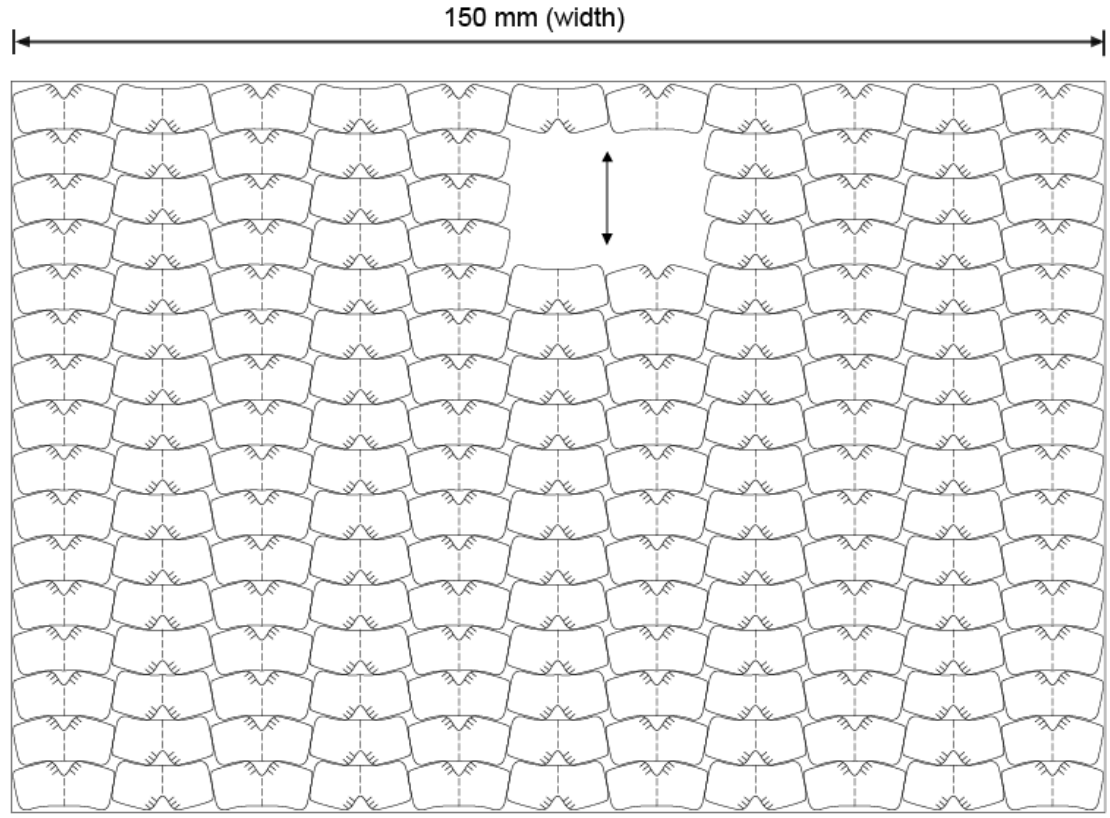


(a) Medium size

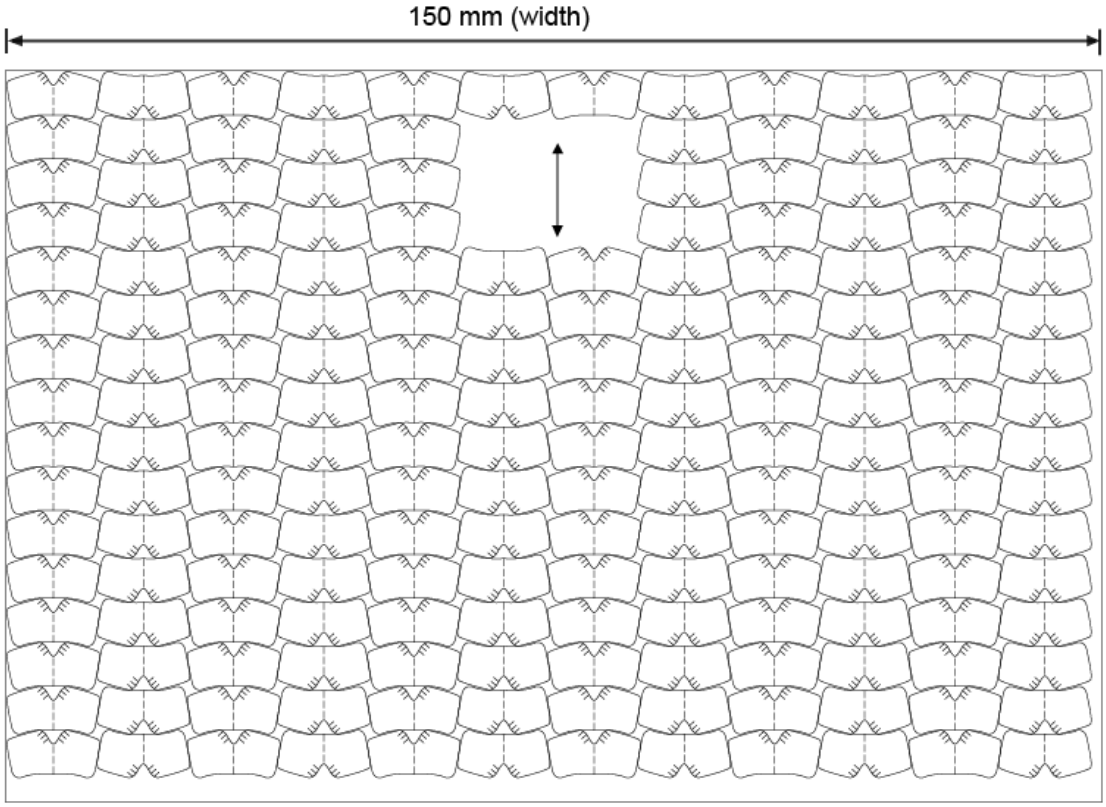


(b) Small size

Figure 6-9: The marker plan for middle-layer woven fabric

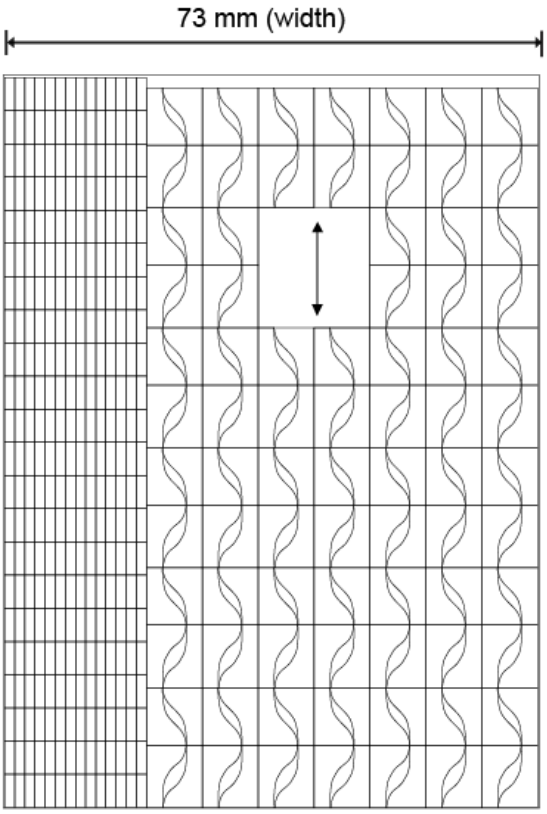


(a) Medium size

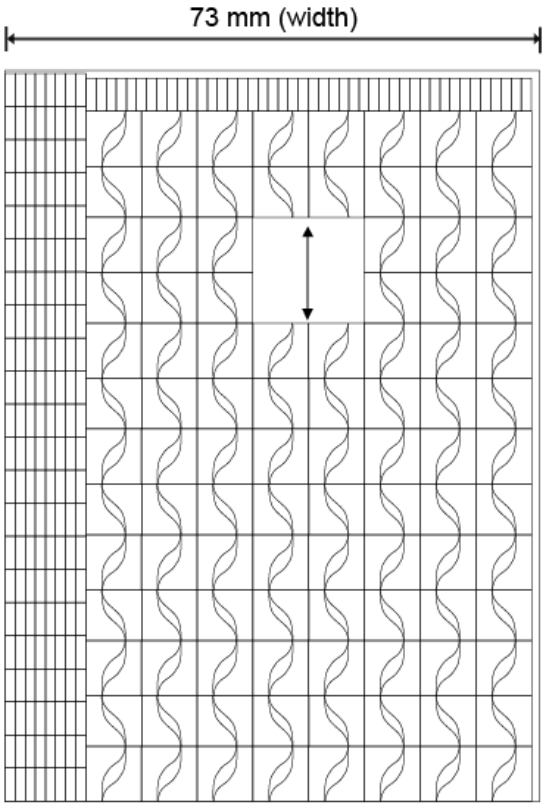


(b) Small size

Figure 6-10: The marker plan for outer-layer knitted fabric



(a) Medium size



(b) Small size

Figure 6-11: The marker plan for non-woven fabric

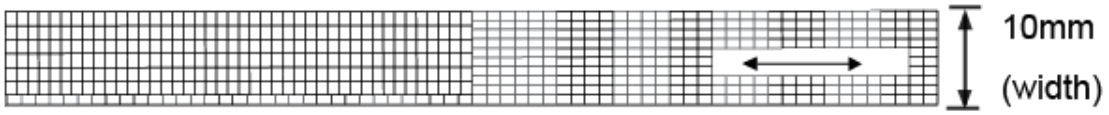


Figure 6-12: The marker plan for hook (in both small and medium sizes)

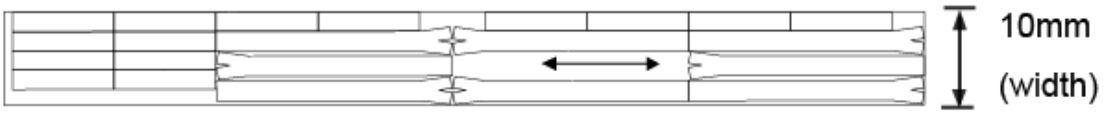


Figure 6-13: The marker plan for loop (in both small and medium sizes)

6.3.3.2 Calculation of Cost of Materials

In this research, one of the design criteria for EP_n is that it is a disposable product. Like most of the medical textile products, the cost of the EP should be calculated with careful consideration. Based on the marker plans above, the cost of materials is shown in Table 6-3.

Table 6-3: Material cost of EP_n

Fabric		Width (m)	Price (HKD/m)	Price/piece (HKD)	
				Small size	Medium size
Inner layer (Knitted)		1.65	18.59	0.089	0.097
Middle layer (Woven)		1.22	18.59	0.103	0.122
Outer layer (Knitted)		1.50	14.22	0.074	0.081
Non-woven	For top band	0.73	8.75	0.007	0.007
	For back band			0.035	0.039
Loop	For top band	0.10	6.56	0.486	0.486
	For back band			0.156	0.156
Hook	For top band	0.10	8.75	0.013	0.013
	For back band			0.016	0.016
Total				1.03	1.08

It is assumed that a worker can manufacture 10 EP_ns per hour. By referring to the bulletin of the Ministry of Labour and Social Security (PRC), the average of the

lowest monthly salary in China is HKD 650 [161], and therefore the labour cost for the EP_n production is around HKD 1.08 per unit.

Table 6-4 shows that the total costs of materials and labour are HKD 2.11 and HKD 2.16 respectively. As compared with the retail prices of HKD 20.80 for EP_1 and HKD 25.28 for EP_2, $EP_{n.v2}$ is highly economical.

Table 6-4: Cost comparisons of prices between EP_1, EP_2 and $EP_{n.v2}$ (Unit: HKD)

$EP_{n.v2}$				EP_1	EP_2
Size	Material cost	Labour cost	Total		
Small size	1.03	1.08	2.11	20.80	25.28
Medium size	1.08	1.08	2.16		

6.4 Second Wear Trial for $EP_{n.v2}$

The second wear trial was also conducted in QMH. The effectiveness, practical use, safety, and appearance of $EP_{n.v2}$ were further evaluated.

6.4.1 Participated Neonates

The procedure and criteria for the neonates recruited were the same as those of the first wear trial. In the second wear trial, 10 neonates were recruited. A summary of their age and body dimensions is presented in Table 6-5 and their detailed information is presented in Appendix 9.

Table 6-5: A summary of subjects participating in the second wear trial

Number of subjects	Age (day)			Head circumference (mm)			Size of $EP_{n.v2}$
	Range	$\bar{x}$	s	Range	$\bar{x}$	s	
7	10.0	6.4	3.6	30	329.3	11.0	Small
3	3.0	4.7	1.5	11	354.0	6.1	Medium

6.4.2 Evaluation of $EP_{n.v2}$ in the Second Wear Trial

The questionnaire survey had six aspects: 1) fitting, 2) design comfort, 3) security and safety, 4) handling performance, 5) appearance, and 6) conclusion. 13 medical staff took part in the questionnaire survey for the second wear trial.

A summary of the questionnaire survey results is presented in Figure 6-14. Obviously, there were no negative comments (namely the score of 1 or 2) on the 12 evaluated items. It is demonstrated that the design modification eliminates the negative design elements in terms of fitting and comfort of the fastening panel, easy donning, and appearance. Figure 6-15 presents the mean and standard deviation of the obtained score for each evaluated item. Except for two items, ease of using hook-and-loops (3.85) and appearance (3.92), the mean score of 10 other items was higher than 4.00, namely attitude of acceptance. The mean score of 7 items (namely comfort of the eye-patch panel, comfort of the fastening panel, security, ease of donning, ease of doffing, ease of using hook-and-loops, and appearance) of the $EP_{n.v2}$ was higher than that of the $EP_{n.v1}$. 2 items (safety and applicability to routine medical treatment/care), which obtained the highest mean score (5.00) in the first wear trial, also received the highest mean score in the second wear trial. This further illustrates

that the modifications not only ameliorate the aspects that the respondents comment on negatively, but also improve the effectiveness and practical use of the EP in a comprehensive manner.

At the end of the questionnaire, a conclusion was drawn by comparing $EP_{n.v2}$ with current EPs used in QMH. Except for 1 medical staff, 12 respondents believed that $EP_{n.v2}$ is better than current EPs based on their practical performance and observation during the wear trial. The exceptional respondent explained the reason why $EP_{n.v2}$ has no prominent advantage over the current EPs, especially the EP_2. The neonate, whom she was conducting the wear trial on, was suffering from a sickness that caused dysphoria, excessive crying and twitching. When the respondent tried to put $EP_{n.v2}$ on the neonate's head, it moved the head vehemently and grabbed one of the bands of $EP_{n.v2}$ which made it difficult to put on the EP. More importantly, the observation was made when the EP was displaced.

In summary, positive comments were obtained on all evaluated items in terms of fitting, design and material comfort, security, safety, handling performance, applicability to medical treatment/care, and appearance. Most of the respondents believe that $EP_{n.v2}$ is better than current EPs used in QMH.

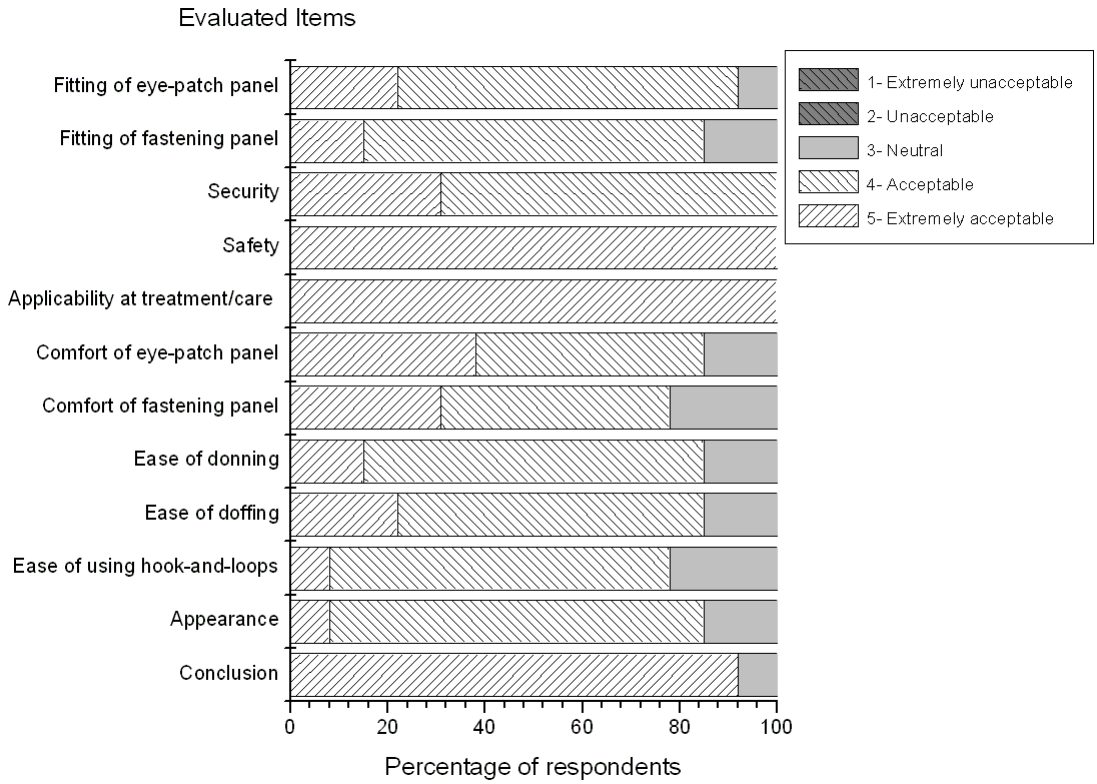


Figure 6-14: Questionnaire survey results in the second wear trial ($EP_{n.v2}$)

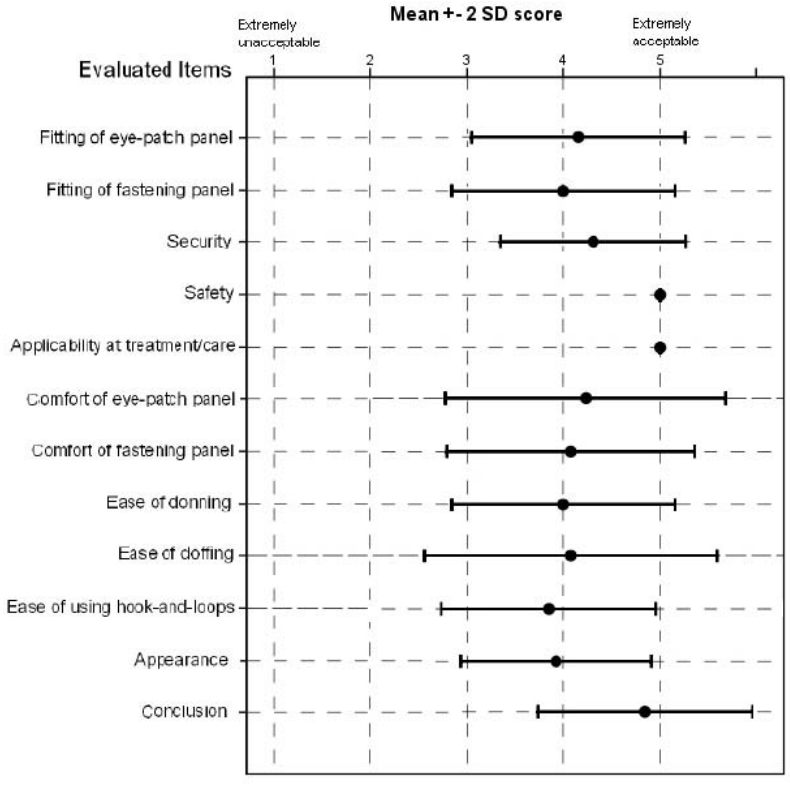


Figure 6-15: The error bar plot of the survey results in the second wear trial ($EP_{n.v2}$)

6.5 Conclusions

The wear trials on the EP_n prototype were conducted in the SCBU of QMH. Five aspects of the $EP_{n.v1}$, including fitting and security, design and material comfort, safety, handling performance, and appearance, were examined by the questionnaire survey. Based on the results, modifications of the EP_n prototype ($EP_{n.v2}$) were made to improve fitting of the back panel, comfort of the back panel, ease of donning, and appearance. A further wear trial was then conducted to evaluate $EP_{n.v2}$. $EP_{n.v2}$ generated a mean score of 5.00 in both safety and applicability to routine medical treatment/care. The mean scores for comfort of the eye-patch panel, comfort of the fastening panel, security, ease of donning, ease of doffing, ease of using hook-and-loops, and appearance also increased remarkably. The satisfied level of $EP_{n.v2}$ obtained from the 13 medical staff was higher than that of the two current EPs.

CHAPTER 7: PHOTO-PROTECTING EVALUATION OF EPS

7.1 Introduction

In this chapter, the measurement of photo-protection, as part of the "evaluation of end-uses" of the protective product development process, is conducted with the aim of evaluating the photo-protecting ability of the EP described in Chapter 6. The flow of the protective product development process is presented in Figure 7-1.

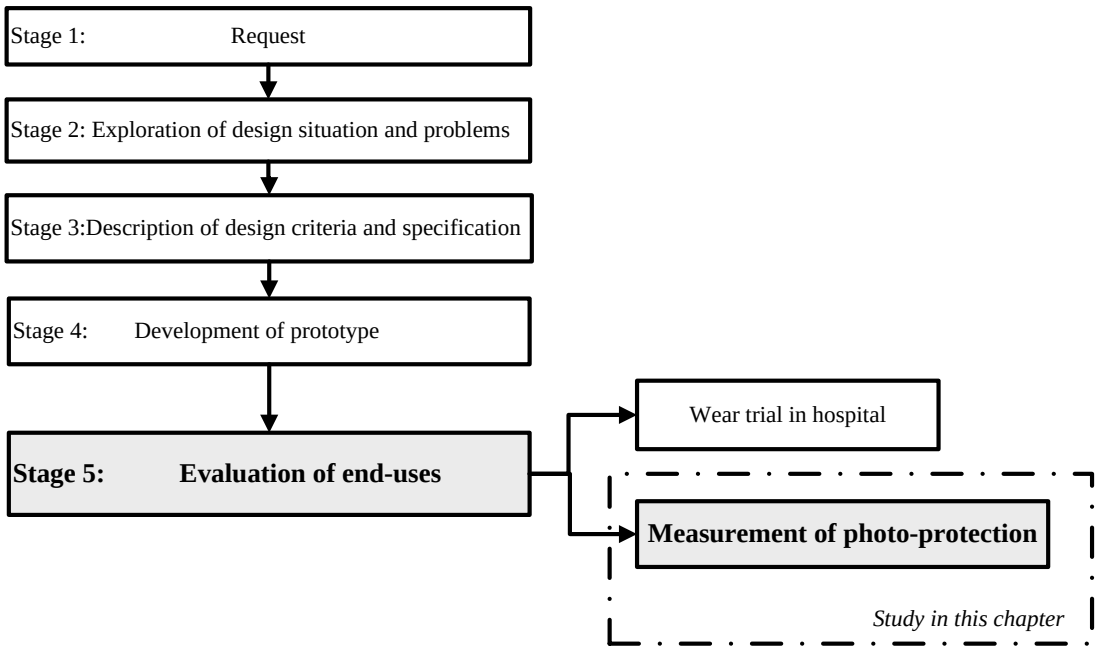


Figure 7-1: Stage 5 of the protective product development process

7.2 A Simulated Clinical Environment for Photo-protection Evaluation

In this research, a simulated clinical environment was set up to mimic a clinical phototherapy environment with various assemblies of light source (i.e. light units,

tubes permutations, locations, directions, and distances). A neonate head model was also developed to determine the relationship between light sources and head positions or angles of the neonates. In this study, a portable spectroradiometer was used to measure light irradiance and illuminance.

7.2.1 Development of a Neonatal Head Model

To evaluate the level of light exposure and protection by the EP in phototherapy treatment, data acquisition instrumentation must be put in the neonate's eye position. A neonate head model is developed in this study to minimize any discomfort or potential hazard caused by the study procedure.

As described in Section 2.4.1 of Chapter 2, computed tomography (CT) is the most useful type of imaging modality for planning surgical management. 3D images of the structure can be reconstructed by selecting them on the slices and piling them up with the use of computer software. Therefore, the CT data of a neonate's head were selected to develop the 3D digital morphology of the neonatal head. The distance of slices was 4 mm and the resolution of slices is 512×512 pixels. Furthermore, the photogrammetry results of the frontal, nasal, maxilla and zygomatic bones of the head model obtained from the 41 measured neonates were merged with the CT data. Based on the above-mentioned 3D contour data, a physical neonatal head model was developed by the Rapid Prototyping System. The procedure of development is shown in Figure 7-2.

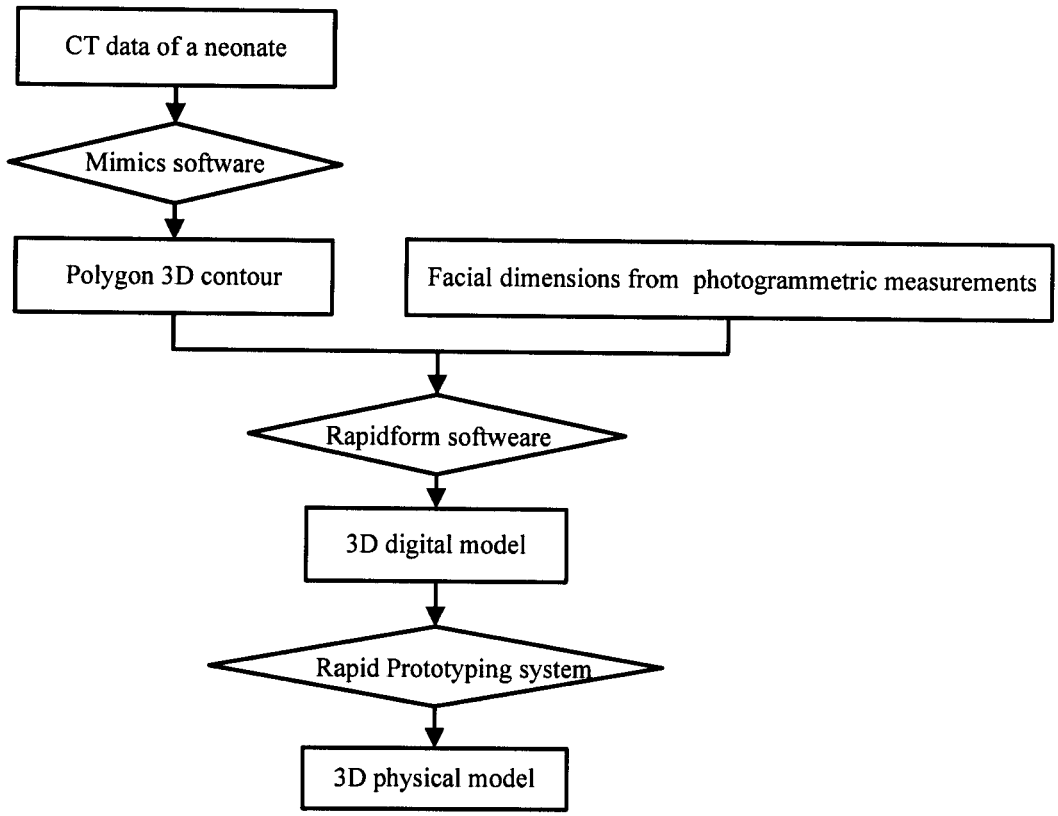


Figure 7-2: Procedure of neonate head model development

The developed neonate head model is shown in Figure 7-3. To measure the displacement of the EP on the neonatal head, a rectangular grid map with 10 mm intervals was marked on the model. A gear with a 15° interval was designed at the bottom of the head model to adjust the angle of the head model.

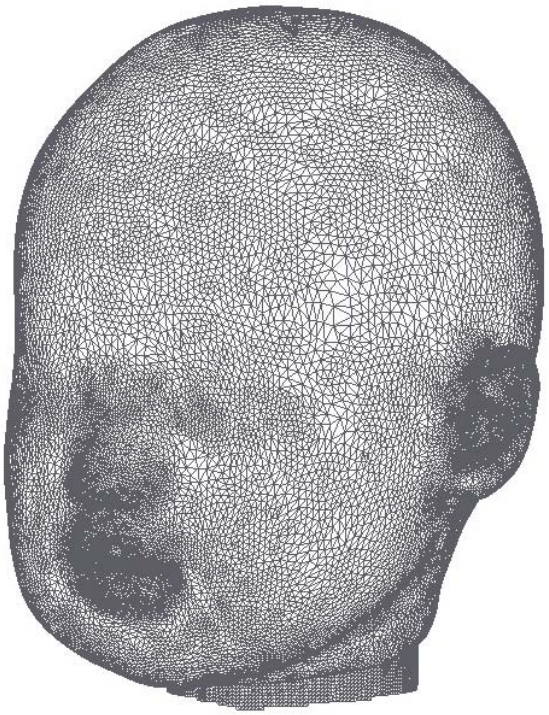


Figure 7-3: The neonate head model

7.2.2 Assembly of Simulated Clinical Environment

An International Light ILT 900 Wideband Rapid Portable Spectroradiometer with a fiber optic/mini waterproof cosine diffuser having a diameter of 14 mm was used for investigating the spectral distribution of light irradiance. The RPS900-R#SM240-IM0P2382-EU detector of the spectroradiometer is compared with the laboratory working standards whose calibrations are traceable to the U.S. National Institute of Standards and Technology and whose procedures are in accordance with the requirements of ANSI/NCSL Z540-1-1994, ISO10012-1:1992(E) and ISO/IEC 17025:2005. In this study, the diffuser of the spectroradiometer was attached to the eye position in the head model to examine the level of light exposure

to the neonatal eyes. The neonatal head model was fixed onto a support stand, on which the model can be turned in different directions so as to simulate the various postures and angles of the neonate head (see Figure 7-4).

The setup of the simulated clinical environment included an Air Shields Isolette® Incubator (for the fluorescent light unit) and a warm bed (for the halogen light unit).

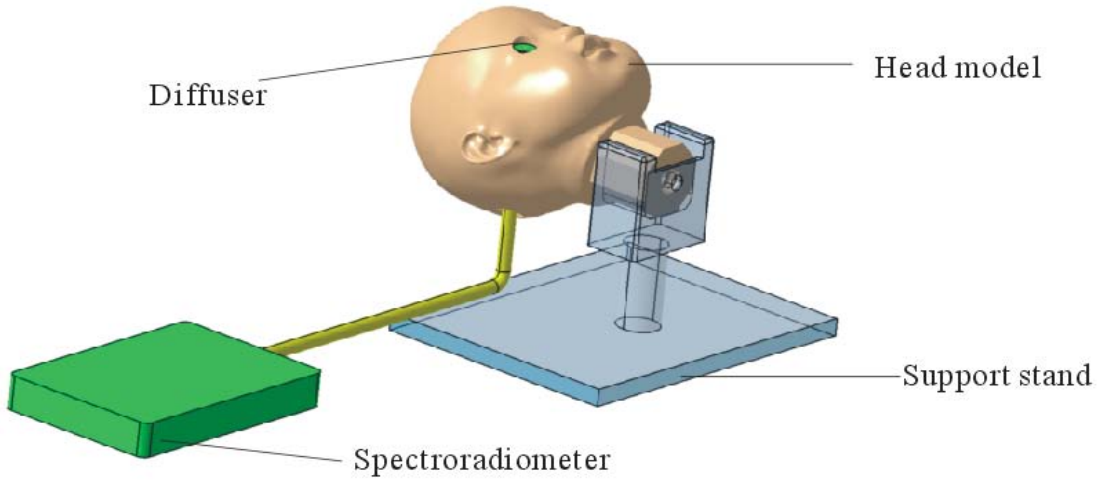


Figure 7-4: Assembly of the data acquisition instrumentation

7.3 Light Conditions at Phototherapy Treatment

Traditionally, the light transmission of phototherapy eye-patches was measured in the way the relative positions of the light source, EP, and detector did not mimic the clinical situation. However, the characteristics of light transmission vary directly with the power source and the light conditions (such as light distance, angle, wavelength, and intensity). Considering the potential hazards of phototherapy light to the cornea and retina, the factors affecting the light conditions in clinical practice must be examined carefully. The research aims to reveal the characteristics of phototherapy

light in clinical conditions, the differences caused by the variation in light units and locations, and locations and directions of the neonate's head.

7.3.1 Experimental Design

In this investigation, a Medela® fluorescent phototherapy unit and an Ohmeda® halogen spotlight unit were used as light sources. The measuring range of the spectroradiometer was regulated as the visible light wavelength of 350-800 nm (with a 2 nm wavelength interval) because visible light may cause retinal damage and a variable degree of visual loss to neonates, and cover the spectrum of bilirubin action ranging from 430 to 475 nm. In clinical practice, factors affecting the light conditions and settings of phototherapy treatment are: 1) light units used, 2) types and numbers of tube permutations, 3) locations of the light units, 4) locations of the diffuser, 5) directions of the diffuser, and 6) the distance between the unit and the diffuser. A summary of the influencing factors is presented in Table 7-1.

Table 7-1: Influencing factors with different levels of phototherapy light

No.	Influencing factor	Levels	Specifications
1	Light units	FL	Fluorescent light unit
		HL	Halogen light unit
2	Tubes permutations	4B	Four blue light tubes
		2B2W	Two blue light tubes and two white tubes blended
		1H	A halogen light unit with a small filter
		2H	A halogen light unit with a middle filter
		3H	A halogen light with a large filter
3	Locations of light units	I	Fluorescent light unit over center of incubator at 0º angle to vertical line (see Figure 7-5)
		II	Fluorescent light unit over center of side of incubator at 45º angle to vertical line (see Figure 7-5)
		III	Fluorescent light at center of back of incubator at 90º angle to vertical line (see Figure 7-5)
		IV	Horizontal cantilever of halogen light (see Figure 7-5)
4	Locations of diffuser	A~F	Diffuser at different points on mattress of incubator (see Figure 7-6)
5	Directions of diffuser	0º~ 180º	Axis of diffuser at angles from 0º to180º with 30º interval to vertical line when diffuser on mattress of incubator (see Figure 7-7)
6	Distance between unit and diffuser	D1	350 mm between unit and diffuser (fixed)
		D2	550 mm between unit and diffuser (fixed)

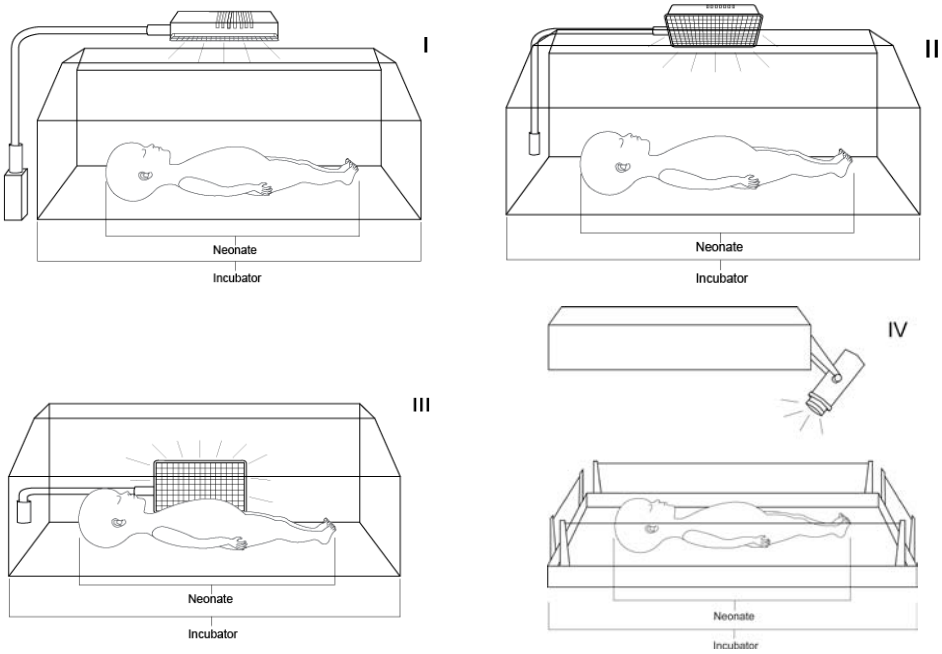


Figure 7-5: Locations of light units

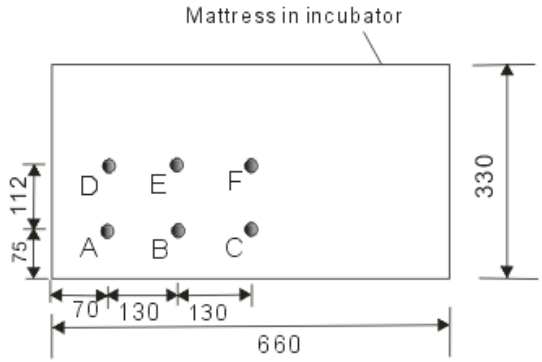


Figure 7-6: Locations of diffuser on mattress (unit: mm)

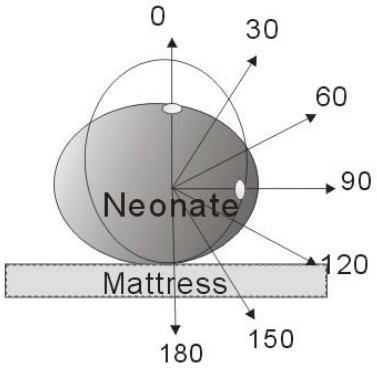


Figure 7-7: Directions of diffuser (unit: °)

Four typical locations of the fluorescent and halogen light unit were extracted

from clinical phototherapy treatment (see Figure 7-5). The diffuser of the spectroradiometer used for the detection of light irradiance was located in 6 different locations so as to simulate the positions of the neonates (see Figure 7-6). In view of the directions of the diffuser, the light irradiance at 7 different angles from 0° to 180° was measured (see Figure 7-7).

An assembly code system for describing the clinical phototherapy light settings was used. The sequence of the assembly code was: light units－tubes permutations－locations of light units－locations of diffuser－directions of diffuser. For example, assembly code FL-4B-I-A-0 means that a fluorescent light with four blue tubes is located over the incubator while the diffuser is located in point A of the mattress in a direction of 0°. The vertical distance between the fluorescent light unit and the diffuser was 350 mm whereas the vertical distance between the halogen light unit and the diffuser was 550 mm in all settings.

7.3.2 Results and Discussions

The spectral distributions of light irradiance with various settings of assemblies were measured, and the total irradiance (in 350-800 nm and 400-500 nm) and the total illuminance (of various setting of assemblies) were also calculated and are summarized in Table 7-2.

When the fluorescent light unit with four blue tubes was put over the center of the incubator with a vertical distance of 350 mm between the unit and the diffuser, the

direction of the diffuser was fixed in a supine position (0°), the spectral distribution of light irradiance was measured at points A, B, C, D, E, and F, illustrating the moving range of the neonate's head on the mattress. The highest values of light irradiance were observed on wavelengths between 400-500 nm (see Figure 7-8). It was found that the wavelength range of 400-500 nm was effective for reducing serum bilirubin. When point E was a typical location of the neonate's head, the total irradiance was 40.35 W/m^2 within 400-500 nm and 46.71 W/m^2 within 350-800 nm. In other words, 86.38% of light converged in 400-500 nm, which is very effective for decreasing bilirubin. The fluorescent light unit is an effective instrument for jaundice treatment.

Table 7-2: The irradiances and illuminances of various settings of assemblies

Assembly code		Irradiance (W/m^2)		Illuminance (lux)
Setting	Variable (*)	350-800 (nm)	400-500 (nm)	
FL-4B-Ⅰ-*-0	A	10.86	8.55	1466.38
	B	28.69	24.60	3044.24
	C	42.46	37.01	4247.8
	D	18.21	14.86	2263.61
	E	46.71	40.35	4925.41
	F	64.31	56.22	6364.63
FL-4B-Ⅰ-E-*	0°	46.71	40.35	4925.41
	30°	32.80	27.93	3507.75
	60°	9.82	7.65	1234.55
	90°	3.51	2.54	517.04
	120°	7.20	5.79	889.06
	150°	5.69	4.46	739.42
	180°	3.16	2.37	458.78
FL-4B-*-E-0	I+II	61.13	53.08	6318.98
	I+III	53.23	45.63	5585.55
	II+II	18.00	14.86	2223.65
HL-*- E-0	1H	230.35	33.78	65269.25
	2H	165.57	24.57	47193.07
	3H	27.86	4.14	8058.29
FL-2B2W-Ⅰ-E-0	-	30.37	18.01	6452.63

The results also showed that the total irradiance and illuminance values obtained from different positions on the mattress were different obviously. The further the distance between the diffuser and the light unit is, the smaller the values of total irradiance and illuminance. The values of total irradiance and illuminance obtained from point F were the highest (64.31 W/m^2 and 6364.63 lux) while the lowest values were obtained from point A (10.86 W/m^2 and 1466.38 lux). It is obvious that the position of the diffuser is a major factor in affecting light irradiance and light illuminance.

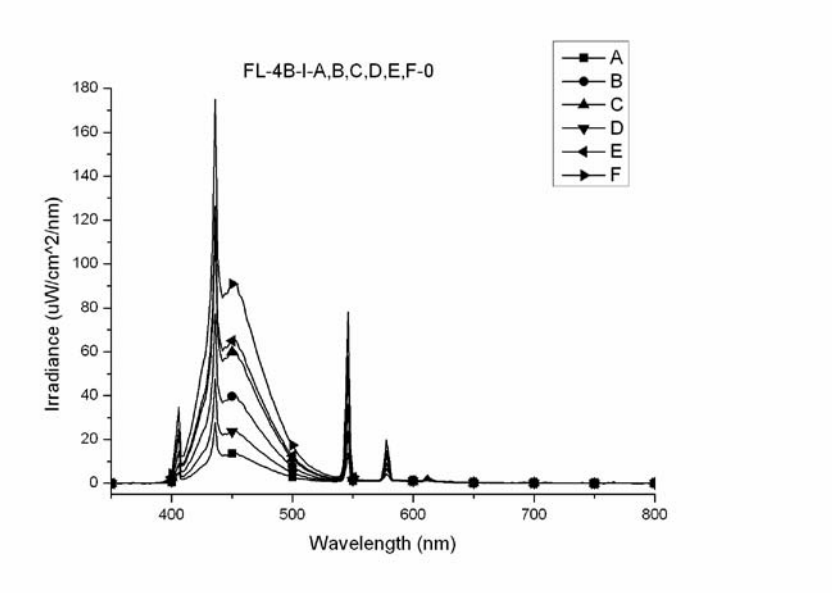


Figure 7-8: Spectral distributions of light from the setting of FL-4B-I-A~F -0°

When the fluorescent light unit with four blue tubes was put over the center of the incubator with a vertical distance of 350 mm between the unit and the diffuser, the position of the diffuser was fixed at point E, and the spectral distribution of light irradiance was measured in directions of 0°, 30°, 60°, 90°, 120°, 150°, and 180° to simulate the neonate's head positions (see Figure 7-9). Of all the directions of the

diffuser, the highest values of total light irradiance and illuminance were obtained when the direction of the diffuser was 0° (46.71 W/m^2 and 4925.41 lux). When turning the diffuser from 0° to 90°, the values of total irradiance and illuminance reduced sharply (32.80 W/m^2 and 3507.75 lux for 30°, 9.82 W/m^2 and 1234.55 lux for 60°, and 3.51 W/m^2 and 517.04 lux for 90°). When the angle moved continuously from 90° to 180°, the low values of light irradiance and illuminance were obtained (within 4.04 W/m^2 and 430.28 lux). The measured values of light irradiance and illuminance obtained from diffuser angles of 120° and 150° were higher than those obtained from diffuser angles of 90° and 180°. The results can be explained by the increased light reflection of the white bedding sheet. The direction between the diffuser and the unit is another major factor in affecting the light irradiance and illuminance.

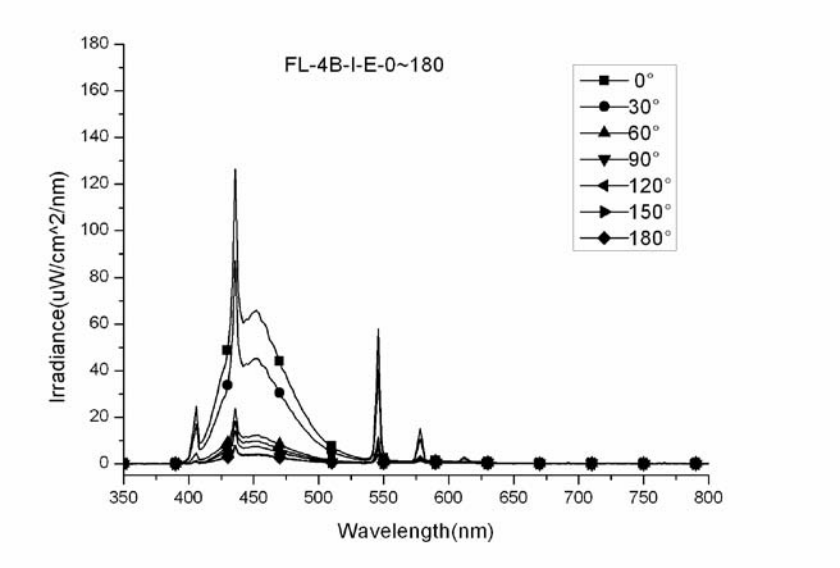


Figure 7-9: Spectral distributions of light from the setting of FL-4B-I-E-0°~180°

When a neonate was affected by severe bilirubin (the bilirubin level close to the

exchange transfusion level at ~340 umol/L after completion of 3 days), multiple units were set up in phototherapy treatment. When the diffuser was located at point E in a supine position (0°), double fluorescent units were set with one overhead (I) and one at the back of the incubator (III), one overhead (I) and one at 45° to the vertical line (II), and both of them at 45° to the vertical line (II). Figure 7-10 presents the spectral distribution of light provided by the double light units. It was observed that the values of light irradiance and illuminance were directly influenced by the locations of the units. The unit located just over the incubator provided the highest values of irradiance and illuminance, while the unit located at the back of the incubator gave the lowest values. The differences can be explained by the variation in directions between the unit and the diffuser. By comparing the double units and the single unit with the diffuser at point E in the direction of 0°, the irradiance value provided by the double unit with one overhead and the other at 45° (I+II) was higher than that provided by a single overhead unit (I). However, the irradiance value obtained by the double unit with one overhead and the other at the back of the incubator (I+III) was slightly higher than that by the single overhead unit. Nevertheless, the irradiance value obtained by the double unit with both at 45° (II+II) was significantly lower than that of the single overhead unit. In view of this, the double unit setting is able to improve the effectiveness of bilirubin reduction by increasing the irradiated area of the body even though its values of irradiance and illuminance do not increase significantly.

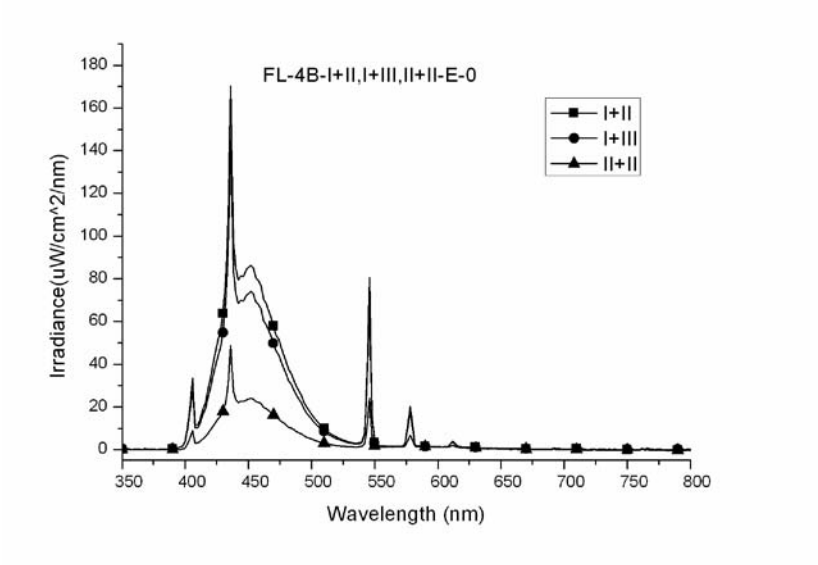


Figure 7-10: Spectral distributions of light from the setting of FL-4B-I+II, I+III, II+III-E-0°

The characteristics of halogen light were examined when the unit was with a small, middle or large filter when the diffuser was at point E in a supine position. Figure 7-11 shows that the peak of spectral irradiance of halogen light was at 640 nm approximately and reduced slowly from the peak. Only 14.84% of halogen light irradiance with a middle filter was in 400-500 nm, which is effective for bilirubin reduction, whereas the halogen light illuminance reached 65269.25 lux for a small filter, 47193.07 lux for a middle filter, and 8058.29 lux for a larger filter. The halogen light unit seems to be less effective than the florescent light unit for reducing bilirubin while it is more dangerous than the fluorescent light unit in terms of retina/cornea damage caused by high illuminance. Thus, the light unit also affects the light irradiance and illuminance.

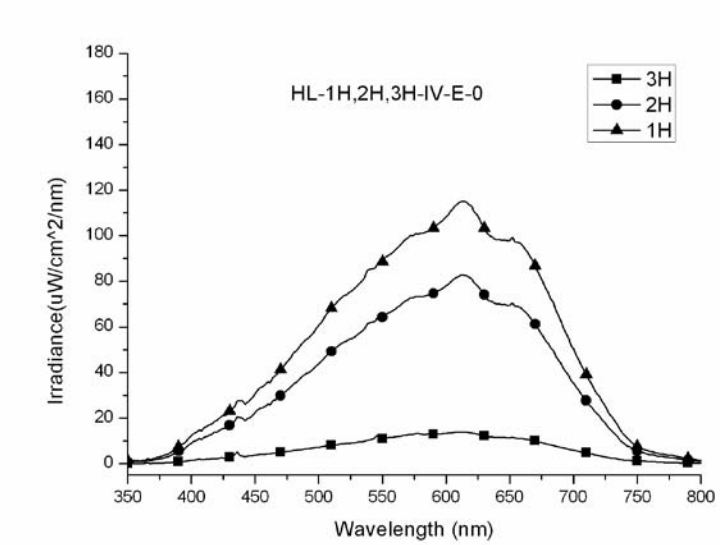


Figure 7-11: Spectral distributions of light from the setting HL-1H, 2H, 3H- E-0°

In a clinical environment, white tubes are mixed with blues tubes to ameliorate caregivers' continual complaints about the blue hue of the light. The effects of the fluorescent light with four blue tubes, and the effects of two white and two blue tubes with the diffuser located at point E in a supine position were examined. Figure 7-12 shows that light irradiance from the unit with four tubes was higher than that with two blue tubes and two white tubes in the wavelength range of 390-530 nm, but lower than that with two blue tubes and two white tubes in other wavelength ranges. It also shows that light irradiance provided by four blue tubes was higher than that with two blue tubes and two white tubes. The light illuminance provided by four blue tubes (4925.41 lux) was lower than that with two blue tubes and two white tubes (6452.63 lux). Results demonstrate that fluorescent light with four blue tubes is better than that with two blue tubes and two white tubes in terms of effectiveness of jaundice treatment and eye safety. When the phototherapy dosage is appropriate, mixed tubes

are used for providing a more comfortable light environment for medical staff.

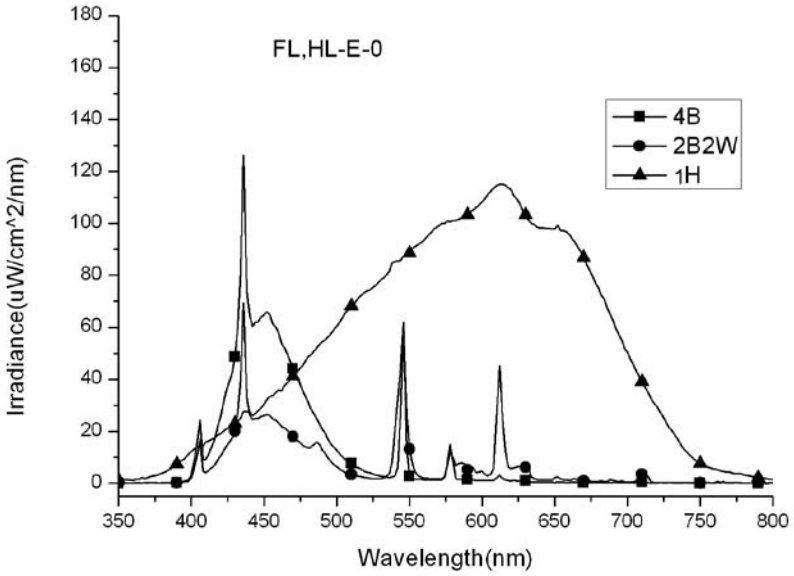


Figure 7-12: Spectral distributions of light from the setting FL-4B, 2B2W- I-E-0°

Amongst various light conditions, fluorescent light unit four blue tubes is the most effective for jaundice treatment and minimizes retinaldamages. Halogen light unit however resulted in the lowest treating efficiency, but high values of light illuminance.

7.3.3 Summary

The characteristics of various assemblies of light units and diffusers are examined above. Light units, tube permutations, the distance between units and diffusers, and the direction between units and diffusers are four major factors in affecting the light irradiance and illuminance. Firstly, the fluorescent light converges within 400-500 nm, which is effective for jaundice treatment, whereas the halogen light disperses on all visible light wavelengths. Thus, the fluorescent light unit has

priority in phototherapy treatment. Secondly, the pure blue-tube permutation is more effective than the mixed-tube permutation for bilirubin reduction. However, the mixed blue-and-white light is applied to clinical practice to ameliorate discomfort caused by the blue hue when its irradiance meets the requirement for dosage. Thirdly, the shorter the distance between the unit and the diffuser is, the larger the total irradiance and illuminance values become. Fourthly, the smaller the angle of the axis joining units and diffusers is, the larger the total irradiance and illuminance values are.

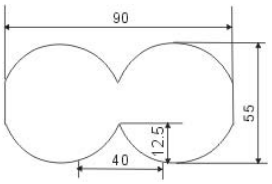
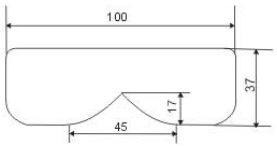
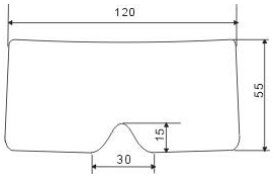
Based on the examination above, a typical assembly of units and diffusers is identified, namely FL-4B-I-E-0. This assembly is applied to the following evaluation of the EP's photo-protecting characteristics and performance.

7.4 Photo-protecting Performance of EPs

7.4.1 Materials Tested

Three EPs were evaluated, including two commercial EPs used in the local Hong Kong hospitals (i.e. EP_1 and EP_2) and a newly developed EP (i.e. $EP_{n.v2}$). The specifications of the eye-patch panels of the three EPs are presented in Table 7-3.

Table 7-3: The specifications of the eye-patch panels of EP_1, EP_2 and $EP_{n.v2}$

Sample code	Materials						Pattern of eye-patch panel (Unit: mm)
	Construction		Content	Color	Weight (g/m^2)	Thickness (mm)	
EP_1	Three-layer composite	Inner	Cotton (weft knitted)	White	365.52	3.75	
		Middle	Polyurethane/ polyester blended (foam)	Grey			
		Outer	Nylon (warp knitted)	White			
EP_2	Three-layer composite covered by an elastic band	Inner	Cotton (weft knitted)	Blue	542.86	2.36	
		Middle	Polyurethane/ polyester (foam)	White			
		Outer	Cotton (weft knitted)	Black			
		Cover	Latex-free (non-woven)	White	155.00	1.92	
$EP_{n.v2}$	Three-layer composite	Inner	Cotton/Modal® blended (weft knitted)	White	401.40	1.30	
		Middle	Cotton (plain woven)	Black			
		Outer	Cotton (weft knitted)	Light			

Note: (1) EP_1: Posey® EP; EP_2: Biliband® EP; $EP_{n.v2}$: newly developed EP.

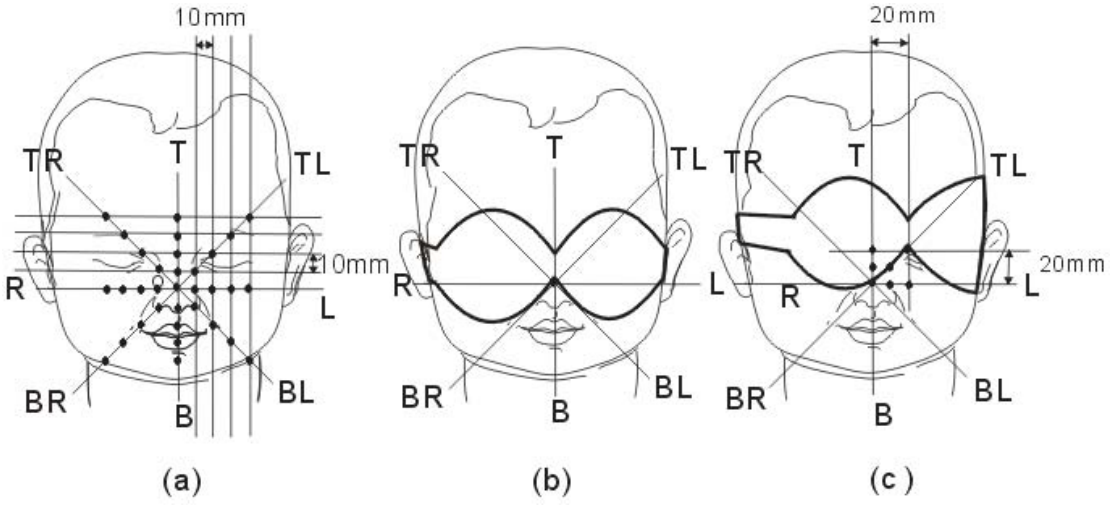
The simulated clinical environment (see Section 7.2) was adopted. A Medela® fluorescent phototherapy unit with four compact blue tubes and an Ohmeda® halogen spotlight unit were used. The background light is typical artificial lighting in the neonatal unit on a 24-hour basis. The light unit, the neonatal head model with a diffuser, and the incubator were assembled as FL-4B-I-E-0 and HL-1H-IV-E-0 respectively.

7.4.2 Experimental Design

The level of light transmission in terms of irradiance and illuminance of the three

EPs was evaluated in optimum and displaced positions. As shown in Figure 7-13, the optimum position of the EPs was defined as the location where the deepest point of the U-shaped cut meets the nose. Based on the grid lines on the head model, the displacement distance and direction were recorded. A total of 8 displacing directions were examined, including right (R), top right (TR), top (T), top left (TL), left (L), bottom left (BL), bottom (B), and bottom right (BR). The displacement distance ranged from 0 mm to 50 mm at 10 mm intervals.

The illuminance magnitude of the EP with direction and distance variation was mapped based on a 600 lux illuminance threshold，over which the risk of the retinopathy of prematurity (ROP) increased significantly [42].



(a) Grid on the head model (b) EP in the optimum position (c) EP in the displaced position

Figure 7-13: Optimum and displaced positions of EPs

7.4.3 Results and Discussions

7.4.3.1 Light Protection of EPs in Optimum Positions

Figure 7-14 illustrates the spectral distributions of irradiance when the three EPs were fixed onto the head model in the simulated clinical environment with fluorescent light setting. The results showed that when the diffuser of the spectroradiometer was shielded by EP_2 or $EP_{n.v2}$, the level of spectral irradiance was lower than that of the ambient light in the wavelength range of 350-800 nm. Even though the maximum spectral irradiance obtained from EP_1 was relatively lower than that of the ambient light, the level of spectral irradiance of EP_1 was higher than the ambient light in the wavelength range of 350-470 nm, which is the typical spectrum of intensive phototheraphy light. As presented in Table 7-4, the total irradiance value of the ambient light was 1.41 ± 0.45 W/m^2, whereas the light irradiance reaching the neonatal eye was 0.67 ± 0.01 W/m^2 for EP_1, 0.35 ± 0.01 W/m^2 for EP_2 and 0.18 ± 0.02 W/m^2 for $EP_{n,v2}$. The total illuminance value of the ambient light was 490.88 ± 163.12 lux, whereas the light illuminance of reaching the neonatal eye was 76.34 ± 1.43 lux for EP_1, 26.97 ± 1.47 lux for EP_2 and 12.66 ± 1.81 lux for $EP_{n.v2}$. All of the three EPs are effective to reduce light illuminance under safety threshold of 600 lux. Amongst, $EP_{n.v2}$ is the most effective one.

As the illuminance of halogen light with small filter was highest among various light setting, the effects of photo-protecting performance were further evaluated under this condition. Figure 7-15 showed, the spectral distribution of halogen light shielded by EP_1 was higher than ambient light while that shielded by EP_2 and $EP_{n.v2}$ were

lower than ambient light. Total irradiances and illuminances of halogen light shielded by three EPs were shown in Table 7-5. Halogen light shielded by EP_1 was 1122.33 lux which was over 600 lux. Obviously, EP_1 was not effective for light protection whilst EP_2 and $EP_{n.v2}$ are effective to protect neonates' eyes.

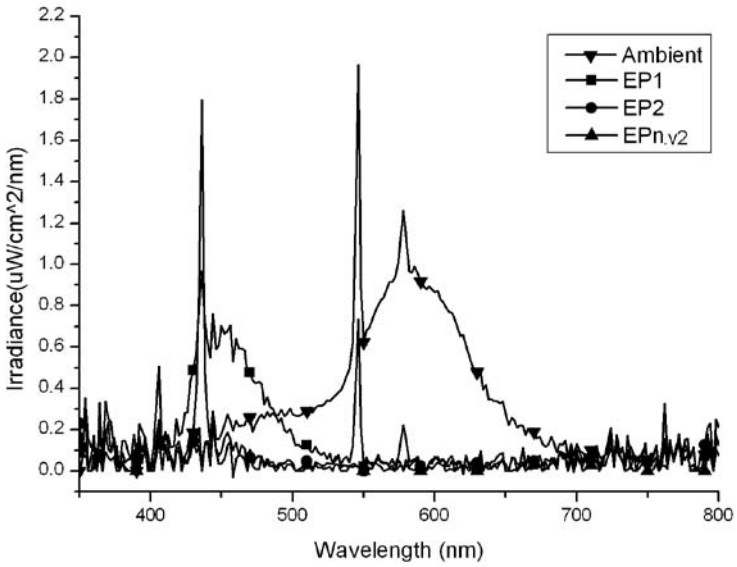


Figure 7-14: Spectral distributions of fluorescent light shielded by EPs

Table 7-4: Total irradiances and illuminances of fluorescent light shielded by EPs

Light conditions	Irradiance (W/m2)		Illuminance (lux)	Illuminance residual (%)
	350-800 nm	400-500nm		
Ambient light at hospital	1.41	0.27	490.88	-
Fluorescent light without EP	46.71	40.35	4925.91	-
Shielded by EP_1	0.67	0.27	76.34	1.20%
Shielded by EP_2	0.35	0.10	26.97	0.55%
Shielded by $EP_{n.v2}$	0.18	0.06	12.66	0.26%

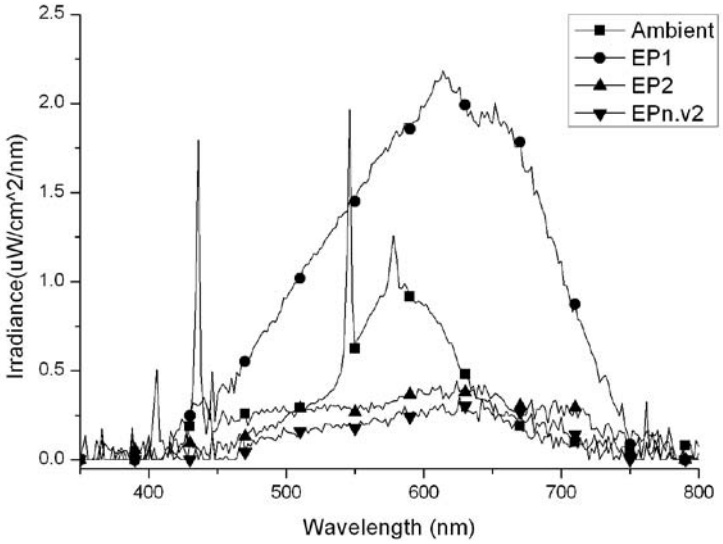


Figure 7-15: Spectral distributions of halogen light shielded by EPs

Table 7-5: Total irradiances and illuminances of halogen light shielded by EPs

Light conditions	Irradiance (W/m2)		Illuminance (lux)	Illuminance residual (%)
	350-800 nm	400-500nm		
Ambient light at hospital	1.41	0.27	490.88	-
Halogen light without EP	230.35	33.78	65269.25	-
Shielded by EP_1	4.01	0.41	1122.33	1.72%
Shielded by EP_2	0.86	0.10	225.35	0.35%
Shielded by $EP_{n.v2}$	0.55	0.05	155.13	0.24%

In addition to the light transmittance property and the performance of the EP fabric, two other factors influencing the effect of eye protection are identified in this study: (1) the covered area of the eye and (2) the light gap. The covered area is determined by the size and shape of the eye-patch panel while the number of light gaps is determined by the match degree between the eye-patch panel, the eye/facial morphology of the neonate, and the displacement level of the eye-patch panel.

When the EP was placed in an optimum position, the eye was completely covered. Therefore, only residual light penetrated the eye-patch panel and leaked

through the light gaps. The results showed that when EPs were used, both irradiance and illuminance were evidently lower than that of the ambient light in the neonatal unit, and illuminances were certainly lower than the 600 lux illuminance threshold. It is concluded that EP_2 and $EP_{n.v2}$ can offer good eye protection in all phototherapy setting when they are placed in an optimum position. Amongst,$EP_{n.v2}$ has the lowest value of illuminance. The light transmittance becomes lower than the required eye protection value while light gaps are eliminated.

7.4.3.2 Light Protection of EPs in Displaced Positions

The level of light illuminance was measured when the four EPs were displaced in different directions and at different distances. In this study, the safety light level in terms of illuminance magnitude was defined as less than 600 lux. Therefore, a square (10 mm × 10 mm) was identified as a safety section with all four apexes of the square obtaining illuminance values less than 600 lux. All safety sections were aggregated as a safety region. The safety region for each EP was marked on the illuminance magnitude maps and a large safety region refers to a more comprehensive EP design which reduces accidental light exposure and minimizes EP repositioning. As shown in Figure 7-16, the safety regions for EP_1 were 400 mm^2 in L-BL-B-BR-R directions. EP_1 could protect neonatal eyes safely even when they fell 30 mm from an optimum position. Nevertheless, potential light exposure could still be found if EP_1 are displaced upwards. In the case of EP_2, the safety region was 400 mm^2 and it was

distributed evenly in all directions. The safety displaced distances in both L and R directions was 20 mm. For the newly developed $EP_{n.v2}$, the safety region was 2000 mm^2 of which, 200 mm^2 fell in L-TL-T-TR-R directions and 1800 mm^2 fell in L-BL-B-BR-R directions. The safety region could further be extended to 20 mm in T direction.

As shown above, the safety region obtained from the three EPs varies substantially from 400 mm^2 to 2,000 mm^2. Among the EPs, the newly developed $EP_{n.v2}$ provides the largest region of light blocking and protects neonatal eyes from accidental light exposure due to EP displacement.

When the EP was displaced, the level of eye protection was determined by the covered area of eyes and the light gaps since the light transmittance of the eye-patch panel was consistent in both optimum and displaced positions. Eyes were covered completely when the EP was displaced within a safety region where only the light gaps could affect the level of eye protection. The illuminance magnitude maps show that the light illuminance reached the neonatal eye when the displaced EPs varied within the region but were still under the safety threshold. It was revealed that the light gaps were changed by the interaction of the EP and the face but none of them worsened the level of eye-protection significantly.

When the edge of the EP approached the eyelid, the directed light could still reach the eye through the light gaps even when the eye was covered completely. Thus, the illuminance value increased sharply and exceeded the safety threshold. It was found that the light gaps in bottom directions affected eye protection significantly

because light usually came in upper front directions when the neonates were in a supine position.

When the eye-patch panel could not cover the neonate's eye fully, the eye was exposed directly to phototherapy light. The illuminance value therefore exceeded the safety threshold. The covered area is affected by the size, shape and design of the eye-patch panel. The correlation coefficient between the size of the eye-patch panel and the safety region was very strong where r = 0.928. The shape and design of the eye-patch panel, and particularly the nose concave for minimizing the light gap, greatly affect the top part of the safety region. The shape conformity of the eye-patch panel and the nose morphology not only minimizes the light gap but also improves the covered area of the eye when the EP is displaced.

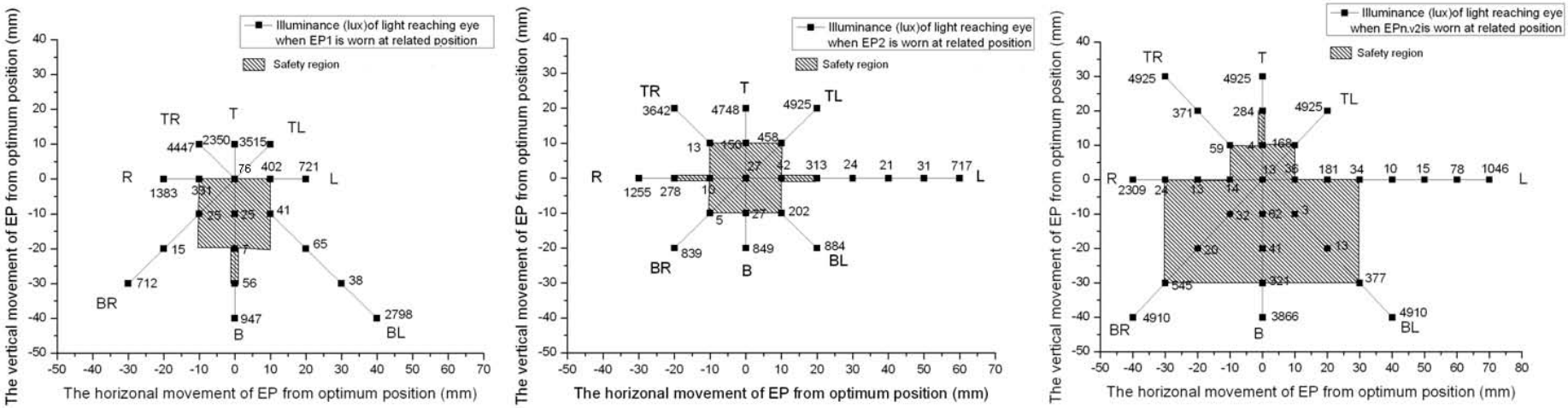


Figure 7-16: Light illuminance magnitude maps of EPs in displaced positions

Comparatively, EP_2 is more effective than EP_1 even though their safety regions are the same (400 mm^2). The safety region of EP_2 was evenly distributed so that it was able to protect the eye comprehensively even when it was displaced. However, when EP_1 was displaced upwards, the eye was exposed to light immediately. The uneven distribution of the safety region was mainly caused by the style design, which determined the relative location of the orbit under the eye-patch panel, the shape of the nose concave, and the interaction of materials and design, which determined the light gaps.

7.5 Security Evaluation of EPs in Practical Use

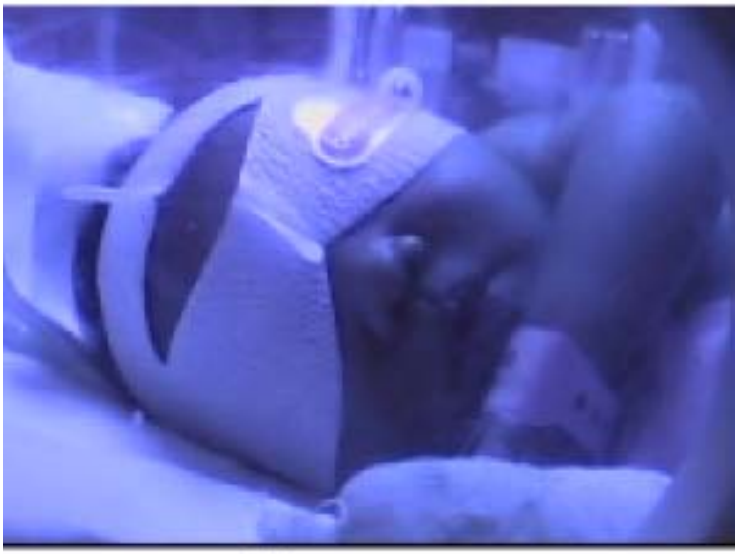
As described in the Introduction, the displacement of EPs is a continual problem in clinical practice. The results of the questionnaire survey described in Chapter 6 show that the respondents believe that $EP_{n.v2}$ resolves the problem based on their clinical observation. To further examine the security of EPs quantitatively, a security evaluation is conducted in this section.

7.5.1 Experimental Design

Ten of the neonates participating in the second wear trial took part in the EP security evaluation. As shown in Figure 7-17, $EP_{1,}$ EP_2 and $EP_{n.v2}$, were worn by each neonate one by one for 180 minutes. By following the safety regions of photo-protection mapped in Figure 7-16, the EPs were repositioned when they were

out of place. The continuous protection and repositioning were recorded by an imaging camera. The periods of continuous photo-protection by the EPs were calculated.

EP1



EP2

EPn.v2

Figure 7-17: A neonate wore EP_1, EP_2 and $EP_{n.v2}$ in the wear trial

7.5.2 Results and Discussions

The time length of holding EPs in position at wear trial is presented in Table 7-6. In the 180-minute test period, the mean of the continuous photo-protecting period was 33.37 min (±29.92 min) for EP_1, 42.83 min (±46.06 min) for EP_2 and 163.64 min (±48.02 min) for $EP_{n.v2}$. It was found that $EP_{n.v2}$ provided the longest continuous photo-protection period while EP_1 provided the shortest. The continuous photo-protection period provided by EP_2 was longer than that by EP_1 but much shorter than that by $EP_{n.v2}$.

Table 7-6: Time length of holding EPs in position at wear trial

Range of Time	Frequency of Displacements		
	EP_1	EP_2	$EP_{n.v2}$
0 – 30 minutes	26	18	1
31 – 60 minutes	18	11	0
61 – 90 minutes	3	2	0
91 – 120 minutes	2	2	1
121 – 150 minutes	0	0	0
151 - 180 minutes	0	2	9
Total No. of displacements	49	35	11
Mean time length of holding EP (minute)	36.02	45.43	163.64
Minimum time length of holding EP (minute)	5.00	5.00	20.00
Maximum time length of holding EP (minute)	120.00	180.00	180.00

The results of the one-way ANOVA (see Table 7-7) also indicated that the EPs influenced the continuous photo-protecting periods significantly ($P = 0.00 < 0.05$). It seems that the security of $EP_{n.v2}$ is much better than current EPs. When the directions of displacement were considered as an influencing factor, the results showed that the directions of displacement have no significant influence on the displacement of the EPs ($p = 0.251 > 0.05$). In other words, there is no bias towards any direction on the

displacement. When the subjects were considered as an influencing factor, the results showed that the subjects had no significant influence on the displacement of the EPs ($p = 0.424 > 0.05$), meaning that the differences of neonatal head morphology did not influence the continuous photo-protecting periods significantly.

Table 7-7: The Factors influencing the displacement of EPs

Factors		Sum of Squares	df	Mean Square	F	Sig.
EPs	Between Groups	10.758	2	5.379	10.115	0.000
	Within Groups	126.038	237	0.532		
	Total	136.796	239			
Directions	Between Groups	5.163	7	0.738	1.300	0.251
	Within Groups	131.633	232	0.567		
	Total	136.796	239			
Subjects	Between Groups	5.254	9	0.584	1.021	0.424
	Within Groups	131.542	230	0.572		
	Total	136.796	239			

7.6 Conclusions

As described in this chapter, a simulated clinical environment was set up, which included a neonate's head model, a spectroradiometer, light sources and an incubator/warm bed to mimic phototherapy treatment in the neonatal unit. The characteristics of clinical phototherapy light with various light units, tube permutations, locations, and directions were examined and analyzed. The light unit, tube permutation, the distance between units and diffusers, and the direction between units and diffusers was identified as the four major affecting factors in light irradiance and illuminance. The levels of light protection by the EPs were evaluated in a typical

phototherapy light condition (FL-4B-I-E-0). The results revealed that the neonate's eyes were safely protected when the EPs were securely held in an optimum position and/or slightly displaced within a safety region. Among the EPs, the newly developed $EP_{n.v2}$ had the best photo-protection performance, providing the largest safety region when it was displaced and also the longest continuous photo-protecting period. The photo-protecting ability of the new developed $EP_{n.v2}$ is better than the other 3 studied EPs.

CHAPTER 8: DEVELOPMENT OF A PRODUCT DEVELOPEMNT MODEL

8.1 Introduction

The Product Development Process (PDP) of developing an EP for neonates used in phototherapy treatment is described in Chapter 7. A comfortable, safe, secure and reliable EP for comprehensive protection of neonates' eyes is developed. In this chapter, the design and development processes of protective textile products for neonates are generalized as a product development model. And a design methodology for fulfilling one of the processes of the product development model, conceptual design, is developed by adopting the Analysis of Interconnected Decision Areas Model (AIDA). The product development model attempts to organize a systematic and theoretical framework to devise a development process and evaluation criteria of protective textile products for neonates during specific care or therapy. It also provides a design methodology for conceptual design of protective textile products for neonates to meet multiple requirements.

8.2 The Product Development Model of Protective Textile Products

Fielden points out that design is the use of scientific principles, technical information and imagination in the definition of a structure, machine or system to perform pre-specified functions with the maximum economy and efficiency [162].

Whiteney remarks, “Product development is the process of converting needs into a technical and commercial solution [163].” However, in a rapidly developing technological world, designers’ work becomes more complex and difficult than before because of a variety of materials, variation in manufacturing methods, the range of required qualities, and pressure on the performance of the finished product. All this leads to universal research in the management of various product design and development processes.

Modeling is a process of abstraction from the “real” world. Each product development process is unique, but the processes may share certain common features or elements. Therefore, it is possible and useful to build qualitative and/or quantifiable models of product development. In addition to the direct contribution to the product development model for controlling and evaluating projects, there is an indirect benefit of model building which helps develop common goals and understanding of tasks among the members of a project team.

In this research, an integrative, externalized and strategy-controlled product development model for protective textile products was formulated. It was constructed by a protective product development process while a design methodology was developed for analyzing design quantitatively to meet specific and general requirements. The model provides a framework of development of protective textile products and tackles associated design fabrication problems so as to achieve an optimum design that meets the specific needs and/or requirements for its end-uses. By following a systematic process and using analytical design techniques, an optimum

solution can be resulted for product development.

The product development model is illustrated in Figure 8-1. The strategies of the process are described as follows.

(1) Request made

The process began with requests of textile product development for neonates. The specific needs were generated from both hospital and home environments for neonatal care and/or treatment, and the neonate's product market, etc.

(2) Exploration of design situations and identification of problems and its structure

The design situation was thoroughly explored in the early stages of the process to determine its true nature. Strategies such as field observation, interviews, questionnaire surveys and literature reviews were applied. As neonates were specific for ethic permission, safety and care/treatment environment, if conditions did not permit direct observation, indirect observation would be carried out in a simulated condition provided by video recorders, photographs, mannequins, computers, etc. In exploration of the situation, constructed, behavioral and natural environments were observed. Regarding protective textile products for neonates, the constructed environment included application of treatment and/or care methods, equipment variations, man-machine interface, etc. The behavioral environment included motions or postures of neonates, caregivers' performance, caregivers' and parents' values and preferences. The natural environment included thermal, light, chemical conditions, etc. Meanwhile, the characteristics and performance of any existing product were

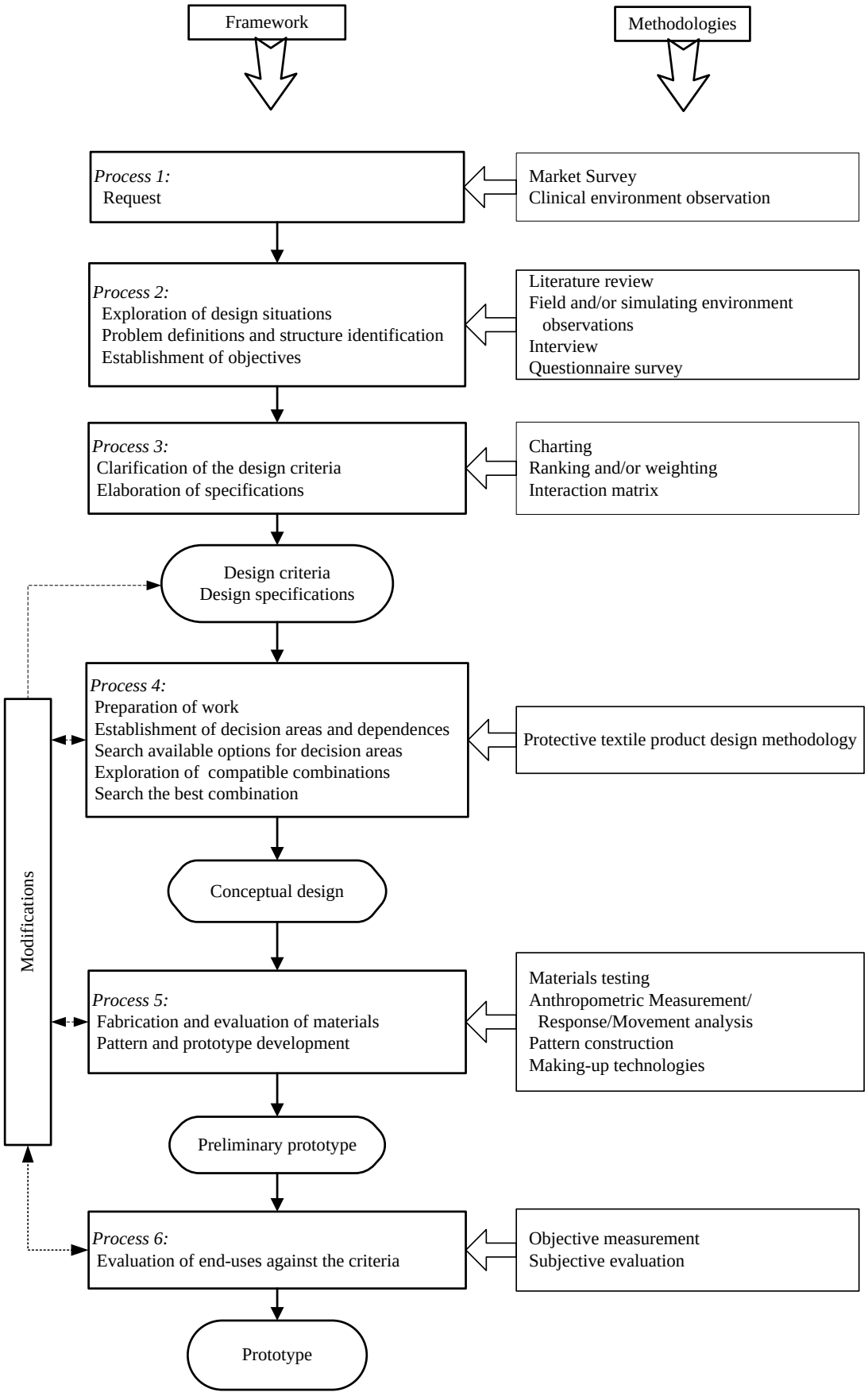


Figure 8-1: The Product development model of protective textile products

investigated. All this are important for establishing design criteria.

Once the exploration was accomplished, the problems should be defined in detail and the objectives of product development should be identified. Meanwhile, the problem structure was perceived. Any critical factor with problems was isolated. With the problem structure, the critical factors were assessed for a specific problem in order to generate criteria and obtain specifications of designs.

(3) Clarification of design criteria and elaboration of specifications

The criteria were ranked or weighed according to their level of importance in relation to performance and end-uses of the product in a complex situation. The design specifications were developed and an interaction matrix of design specifications was constructed to illustrate the relationship between each pair of specifications. The matrix provides a clear picture for the next stage of design and development of a prototype.

(4) Conceptual design

It is a process of integrating design criteria and formulating a number of possible solutions. The product design methodology of the Analysis of Interconnected Decision Areas (AIDA) was adopted. The details of the design methodology are described in the next section.

(5) Development of prototypes

Based on the results of the conceptual design, anthropometric measurement, fabrication and evaluation of materials, and pattern construction and making-up technologies, a product prototype was developed.

(6) Evaluation of end-uses and modifications

The end-uses of the prototype were evaluated to examine the prototype's effectiveness and practicality. Objective evaluation was conducted for measurable qualities, especially protective performance while subjective comments were also collected for evaluation of practicality and comfort. Based on the results of evaluation, modifications were continuously conducted to reduce the weakness of preliminary prototype until all results of evaluation met the design criteria.

8.3 The Development of the Design Methodology of Protective Textile Products

As shown above, the design phase (Process 4) is one of the most creative processes of the Product Development Model. In apparel design, the design process is commonly regarded as resembling a "black box", which means it can hardly be visualized [164]. However, this traditional design method is unlikely to provide an optimum solution to the critical and comprehensive problems in a single protective product. In EP design, the critical design factors, such as fitting of EPs and security, should be considered for improving photo-protection of EPs. Meanwhile, the physical and physiological comfort, hospital safety, easy handling and appearance also need consideration. Therefore, a strategic-control design system combining a creative approach is needed. A strategic-control design methodology based on the Analysis of Interconnected Decision Areas Model (AIDA) technique was established for the design of protective textile products.

8.3.1 Design Methodology of Protective Textile Products

The AIDA Model illustrates the interdependencies and relations between decisions, and therefore selects the best compatible solutions to product design. In view of this, the AIDA Model was applied to formulating the design methodology so as to meet the multiple requirements for protective textile products. The framework of the design methodology including five stages is shown in Figure 8-2.

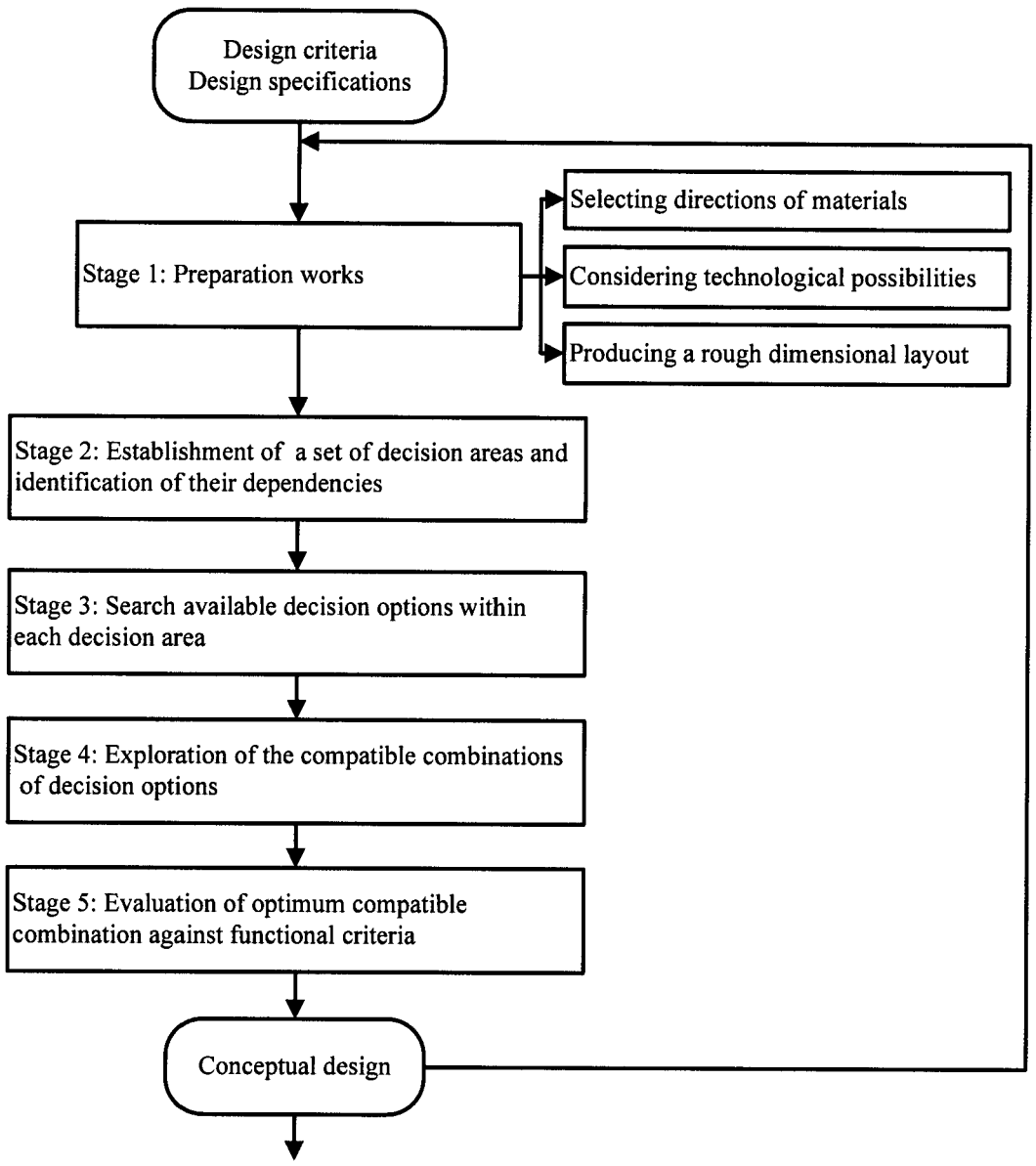


Figure 8-2: The framework of the design methodology for protective textile products

(1) Preparation work

Based on the design specifications, the first stage of work includes initial research and analysis of potential materials, possible product dimensions and manufacture technologies, etc.

(2) Establishment of a set of decision areas and identification of dependencies between decision areas

The next stage is defining the decision area as an element of the problem in which a choice among various acceptable answers is needed. Once the set of decision areas is established, the inter-dependencies between each pair of decision areas should also be identified so as to clear which decisions should be considered jointly. To resolve the difficulty of human mind grasping the significance of many variables and the interrelationship involved in a complex decision with many dependencies, a diagram of decisions and their dependencies is drawn.

A sample is shown in Figure 8-3. The node of the graph represents the distinct decision areas, while a line represents the interdependence between two decision areas. The lines represent a mutual relationship between two decision areas while the absence of a link represents a supposition that the decision can be dealt with independently. It is important to note that it is not a directed graph with some decisions preceding others. And dependencies are not defined as transitive. In Figure 8-3, Decision Area 2 has relationships with Decision Area 1 and Decision Area 3 respectively while Decision Areas 1 and 3 are independent.

Figure 8-3: A sample of decision area graph

(3) Search each decision area for available options

The next stage is to search each decision area for all potential options. To clearly define the nature of the dependencies between the corresponding linked decision areas, one must explicitly define the choices that are available within each decision area. Typically, the feasibilities of options are assessed preliminarily to eliminate the unfeasible options based on the results obtained from preparation work and design experience.

(4) Exploration of the compatible combinations

In this stage, a compatible set describes any combination of option, the set drawn from each of the decision areas, which is feasible in the sense that it does not violate any of the compatibility rules included in the current formulation of the decision problem.

An algorithm which can calculate the α-combinations of options is illustrated as below using a set of decision areas showed in Figure 8-4.

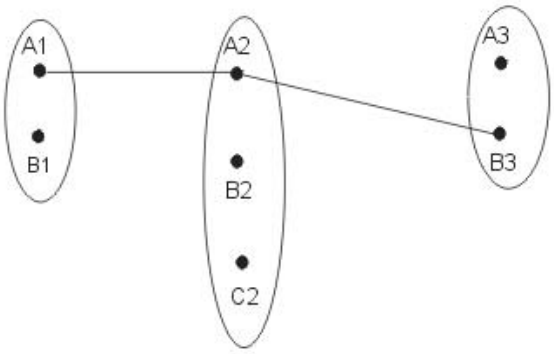


Figure 8-4: A sample of decision options

$$\alpha = \alpha(A1) + \alpha(B1) + ... \tag{8-1}$$

An entry of A_{ij} is 1 if the two options are compatible, otherwise it is 0.

$$A_{ij} = \begin{matrix} \\ A_i \\ B_i \end{matrix} \begin{matrix} \begin{matrix} A_j & B_j & C_j \end{matrix} \\ \begin{bmatrix} 0 & 1 & 1 \\ 1 & 1 & 1 \end{bmatrix} \end{matrix} \tag{8-2}$$

$$A_{12} = \begin{bmatrix} 0 & 1 & 1 \\ 1 & 1 & 1 \end{bmatrix}, \quad A_{13} = \begin{bmatrix} 1 & 1 \\ 1 & 1 \end{bmatrix}, \quad A_{23} = \begin{bmatrix} 1 & 0 \\ 1 & 1 \\ 1 & 1 \end{bmatrix}$$

$C_{23}(a_1)$ is defined as a matrix in which the rows are associated with the first row of A_{12}, and the columns with the first row of A_{13}.

Namely, $C_{23}(a_1) = \begin{matrix} \\ 0 \\ 1 \\ 1 \end{matrix} \begin{matrix} \begin{matrix} 1 & 1 \end{matrix} \\ \begin{bmatrix} 0 & 0 \\ 1 & 1 \\ 1 & 1 \end{bmatrix} \end{matrix}$

$$\alpha(A_1) = \sum (A_{23} \times C_{23}(a_1)) \tag{8-3}$$

Namely, $\alpha(A_1) = \sum \left(\begin{bmatrix} 1 & 0 \\ 1 & 1 \\ 1 & 1 \end{bmatrix} \times \begin{bmatrix} 0 & 0 \\ 1 & 1 \\ 1 & 1 \end{bmatrix} \right) = \sum \begin{bmatrix} 0 & 0 \\ 1 & 1 \\ 1 & 1 \end{bmatrix} = 4$

Similarly, $\alpha(B_1) = 5$

Thus, $\alpha = \alpha(A1) + \alpha(B1) = 9$

By using straightforward generalization, a given complete graph K_N can be

reduced by one point at a time. Thus, K_3 is obtained eventually.

(5) Evaluation of optimum compatible combinations against functional criteria

The compatible combinations that are elaborated must be evaluated by specific end-uses and functions. For protective product development, the major criteria are of a technical nature, such as its designated product function, end-uses, safety and comfort.

8.3.2 Application of Design Methodology to EPs

In this study of EP design and development, the design methodology for protective textile products was adopted. The details of the design process are shown below.

(1) Preparation work

It includes examination of new materials, manufacturing technologies and products so as to enhance the conceptual and creative capability of the product design.

The work for EP design comprises initial research and analysis of suitable fabric materials, fastening systems, fixing methods, etc., in accordance with the specific functional EP requirements, such as photo-protection, comfort and safety, etc. In view of this, the criteria and options of fabrics for the eye-patch panel, the fastening system and the fixing method were investigated and are summarized as follows.

The textile material used must be able not only to shield phototherapy light safely,

but also to provide optimum physical comfort and minimize eye irritation, or other serious ocular complications, such as eye infection. The fabric criteria include photo-protection, comfort, safety and aesthetic appearance. The options include 1) single-layer and 2) 2- or 3-layer composite structures.

In view of the fastening system, the selection criteria are good elasticity, security with minimum displacement, easy to use, comfort, and safety, etc. It is crucial that a fastening system can help cover the neonate's eye securely and fit different shapes and sizes of the neonate's head.

The seams and stitches used should be inexpensive and comfortable with good seam elasticity and simple processes.

(2) Establishment of decision areas and identification of dependencies between decision areas

A set of decision areas was established to maximize eye protection under phototherapy light. The fitting, comfort, characteristics of head morphology, movement of neonates were also considered.

Decision Area 1 (profile of the eye-patch panel) aims to develop an optimum fitted EP to protect the neonate's eye from various light directions and conditions when the EP is in an optimum position.

Decision Area 2 (shape of the eye-patch panel) aims to provide a maximum covering area with safety (e.g. avoiding suffocation of neonates) and comfort (e.g. avoiding the spiculate shape) so as to maximize the safety region of photo-protection.

Decision Area 3 (fixing location of the eye-patch panel and fastening panel) aims

to fix the eye-patch panel to the head in a fitting manner.

Decision Area 4 (number of fixing band(s)) aims to fix the EP effectively and conveniently.

Decision Area 5 (locations of fixing band(s)) aims to select the most effective location of band(s) so as to fix the EP effectively when the neonate's head connects or rubs against the incubator or cot.

As shown in Figure 8-5, the fixing location of the eye-patch panel and the fastening panel, the number of fastening band(s), and locations of fastening band(s) are interdependencies in the five decision areas.

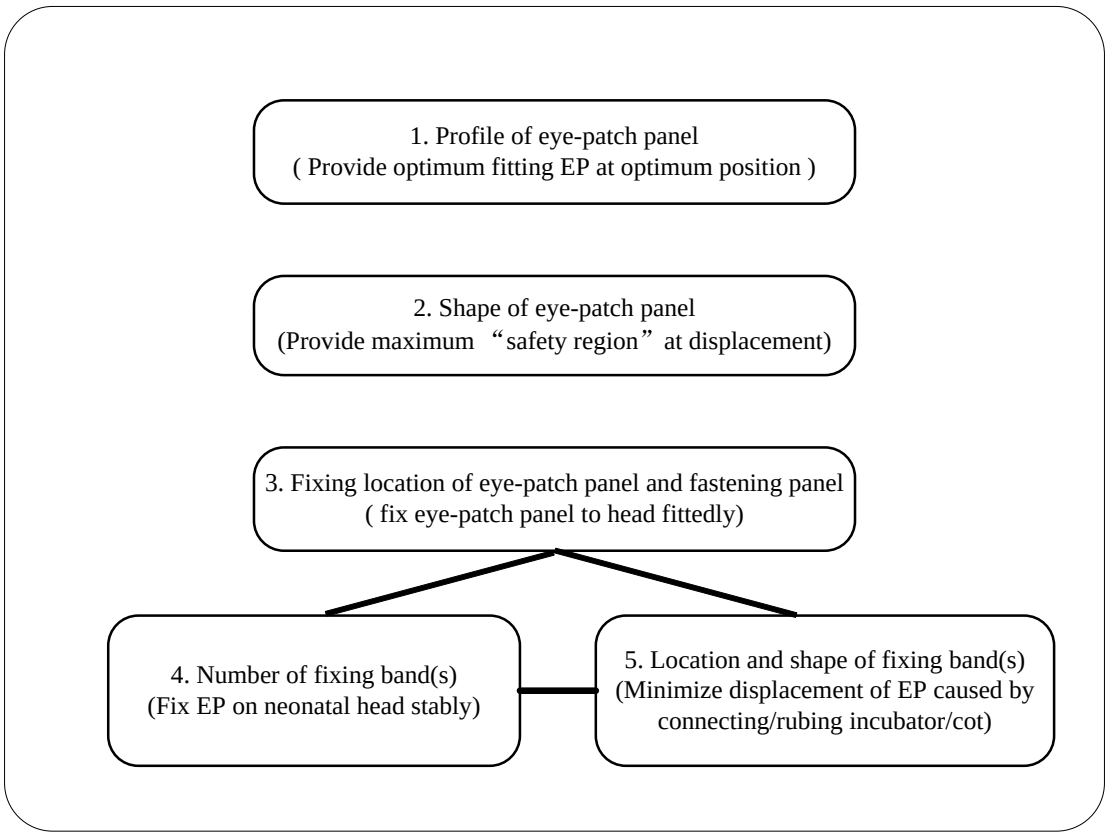


Figure 8-5: A Set of decision areas of EPs

(3) Determination of options within decision areas and identification of their interdependencies

The options for each area are generated and presented in Table 8-1.

(a) The profile of most current eye-patch panels is 2D flat. However, a 3D profile is also a choice as craniofacial morphology is complicatedly 3D.

(b) The shapes of eye-patch panels are various and can be summarized into two types- circular and rectangular.

(c) According to the head morphology, the top, right and left edges of the eye-patch panel are the possible connecting locations of the eye-patch panel and the fastening panel. However, connections only on the top edge are difficult to fix on the neonate's head.

(d) The number of bands is one of the important factors in fixing the EP effectively on the neonate's head. Typically, multiple bands are easier to establish a stable fixation of EPs. However, too many bands cause problems such as inconvenient donning/doffing, entanglement and potential strangulation. Based on the medical staff's comments, three bands or more are unacceptable in practical use.

(e) The location of bands is another main factor in influencing the fixing effect. Based on the anatomical characteristics of the skull (such as size and shape), the occipital bone is the most important for effective fixation. There are three kinds of locations of fixing bands, encasing, partly encasing or exposing the occipital bone. However, partly encasing the occipital bone such as EP_1 caused easy displacement according to the medical staff's observation, who strongly suggested eliminating this

option from the new EP design.

Table 8-1: Decision areas and related options for EP design

Decision areas	Available options		Eliminated options
	A	B	
1) Profile of eye-patch panel	2D flat	3D	-
2) Shape of eye-patch panel	Circular	Rectangular	-
3) Fixing locations of eye-patch and fastening panel	Top and lateral edges of eye-patch panel	Lateral edges of eye-patch panel	Top edges of eye-patch panel
4) Number of fixing band(s)	One	Two	More than two
5) Locations of fixing band(s)	Encasing occipital bone	Exposing occipital bone	Partially encasing occipital bone

(4) Exploration of the compatible combinations

The compatibilities of options in each decision area were identified. As shown in Figure 8-6, A3 (top and lateral edges of the eye-patch panel) and A4 (one band), A3 (top and lateral edges of the eye-patch panel) and B5 (exposing the occipital bone), A4 (one band) and B5 (exposing the occipital bone) were incompatible. For A3 and A4, the fixation of the fastening system located on the top and lateral edges of the eye-patch panel requires at least two bands. For A3 and B5, two bands fixed on the top and lateral edges respectively could not avoid the occipital bone totally with stable fixation. If there is only one band, the occipital bone must be encased so as to maintain the EP in a secure position (i.e. incompatibility of A4 and B5).

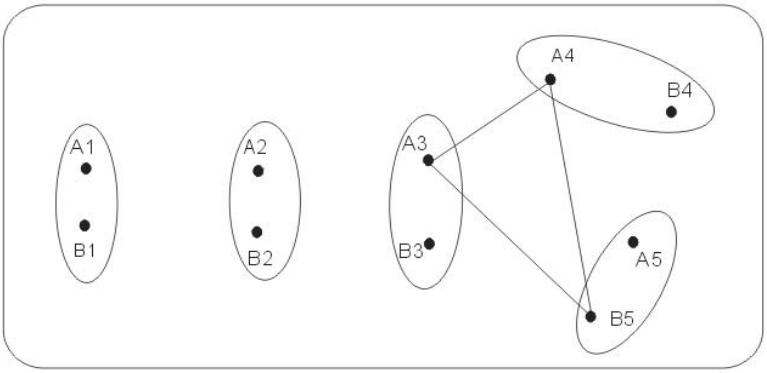


Figure 8-6: The option graph of EP

Then the compatible sets were calculated according to the algorithm presented in the section above.

For α3, α4 and v5, $A_{34}=\begin{bmatrix}0 & 1\\ 1 & 1\end{bmatrix}$, $A_{35}=\begin{bmatrix}1 & 0\\ 1 & 1\end{bmatrix}$, $A_{45}=\begin{bmatrix}1 & 0\\ 1 & 1\end{bmatrix}$

$$\alpha_{345}=\alpha(A_3)+\alpha(B_3)$$
$$=\sum\left(\begin{bmatrix}1 & 0\\ 1 & 1\end{bmatrix}\times\begin{bmatrix}0 & 0\\ 1 & 0\end{bmatrix}\right)+\sum\left(\begin{bmatrix}1 & 0\\ 1 & 1\end{bmatrix}\times\begin{bmatrix}1 & 1\\ 1 & 1\end{bmatrix}\right)$$
$$=\sum\begin{bmatrix}0 & 0\\ 1 & 0\end{bmatrix}+\sum\begin{bmatrix}1 & 0\\ 1 & 1\end{bmatrix}$$
$$=1+3$$
$$=4$$

Then, $\alpha_{12345}=4\times 4=16$

Thus, the total number of combinations is 16 and the combinations are enumerated in Figure 8-7.

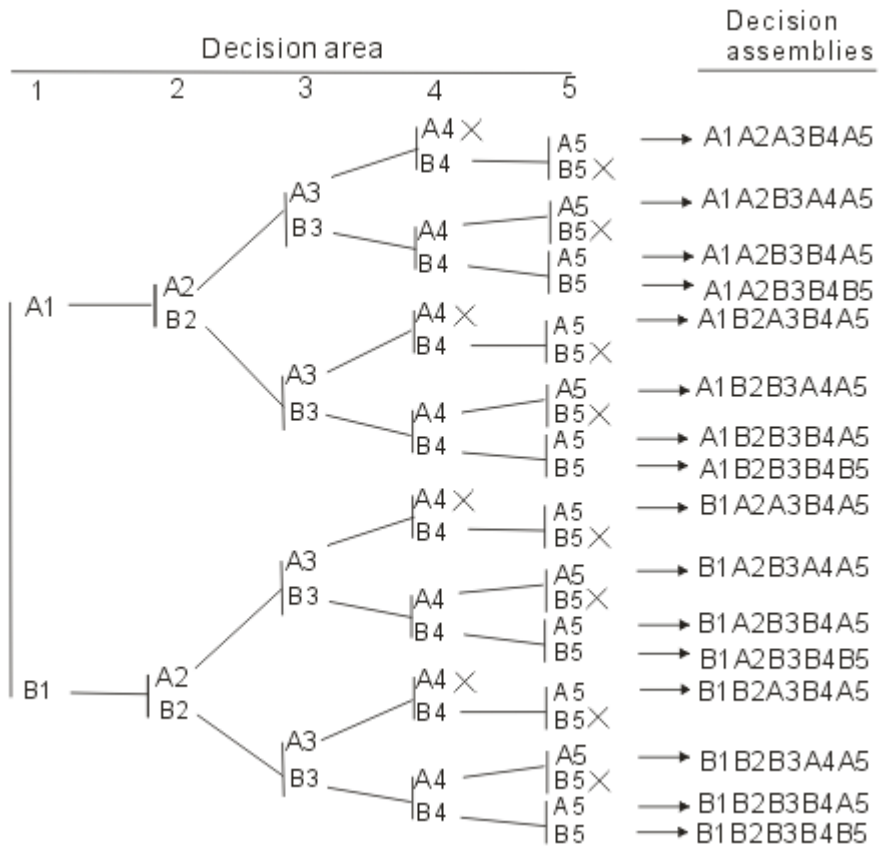


Figure 8-7: The decision tree of EP

(5) Evaluation of optimum compatible combination

To evaluate the optimum compatible combination, the scores of the options were assigned based on the subjective assessment results of four initial designs responded by medical staff at QMH (see Section 5.3 of Chapter 5). The assigned scores of the design options in each decision area are presented in Table 8-2 and the total scores for each compatible combination are presented in Table 8-3.

Table 8-2: Scores for each of the design options in decision areas

Options		Score	Reasons
1. Profile of eye patch panel			
A	2D flat	1	Potential light gap and pressure on eye ball or orbit; easily displaced
B	3D	2	Reducing light gap and relieving pressure on eye ball or orbit; minimizing EP displacement
2. Shape of eye patch panel			
A	Circular	1	Reducing safety region of EP displacement and movement of neonates
B	Rectangular	2	Enlarging safety region of EP displacement
3. Fixing locations of eye-patch and fastening panel			
A	Top and lateral edges of eye-patch panel	1	Band located at top and lateral edges of eye-patch panel generating unbalanced force, thus causing light gap and displacement
B	Lateral edges of eye-patch panel	2	Bands located at right and left edges of eye-patch panel generating balanced force, thus minimizing light gap and displacement
4. Number of fixing bands			
A	One	1	Ease to use but easily displaced
B	Two	2	EP held securely in place
5. Locations of bands			
A	Encasing occipital bone	1	Rubbing against cot/pillow and causing EP displacement
B	Exposing occipital bone	2	Minimum rubbing against the cot/pillow

Table 8-3 shows the compatible combination B1B2B3B4B5 obtained the highest total score among the 16 combinations. The design combination included B1) **3D**, B2) **rectangle eye-patch panel**, B4) **two bands of fastening system**, and B5) **exposing the occipital bone** while B3) **fastening system fixed at the lateral edges of eye-patch panel**. The obtained conceptual design is illuminated in Figure 8-8.

Table 8-3: The total score for each combination

Options of decision areas	A1	B1	A2	B2	A3	B3	A4	B4	A5	B5	
Score	1	2	1	2	1	2	1	2	1	2	Total
A1A2A3B4A5	1	0	1	0	1	0	0	1	1	0	6
A1A2B3A4A5	1	0	1	0	0	1	1	0	1	0	6
A1A2B3B4A5	1	0	1	0	0	1	0	1	1	0	7
A1A2B3B4B5	1	0	1	0	0	1	0	1	0	1	8
A1B2A3B4A5	1	0	0	1	1	0	0	1	1	0	7
A1B2B3A4A5	1	0	0	1	0	1	1	0	1	0	7
A1B2B3B4A5	1	0	0	1	0	1	0	1	1	0	8
A1B2B3B4B5	1	0	0	1	0	1	0	1	0	1	9
B1A2A3B4A5	0	1	1	0	1	0	0	1	1	0	7
B1A2B3A4A5	0	1	1	0	0	1	1	0	1	0	7
B1A2B3B4A5	0	1	1	0	0	1	0	1	1	0	8
B1A2B3B4B5	0	1	1	0	0	1	0	1	0	1	9
B1B2A3B4A5	0	1	0	1	1	0	0	1	1	0	8
B1B2B3A4A5	0	1	0	1	0	1	1	0	1	0	8
B1B2B3B4A5	0	1	0	1	0	1	0	1	1	0	9
B1B2B3B4B5	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**1**	**0**	**1**	**10**

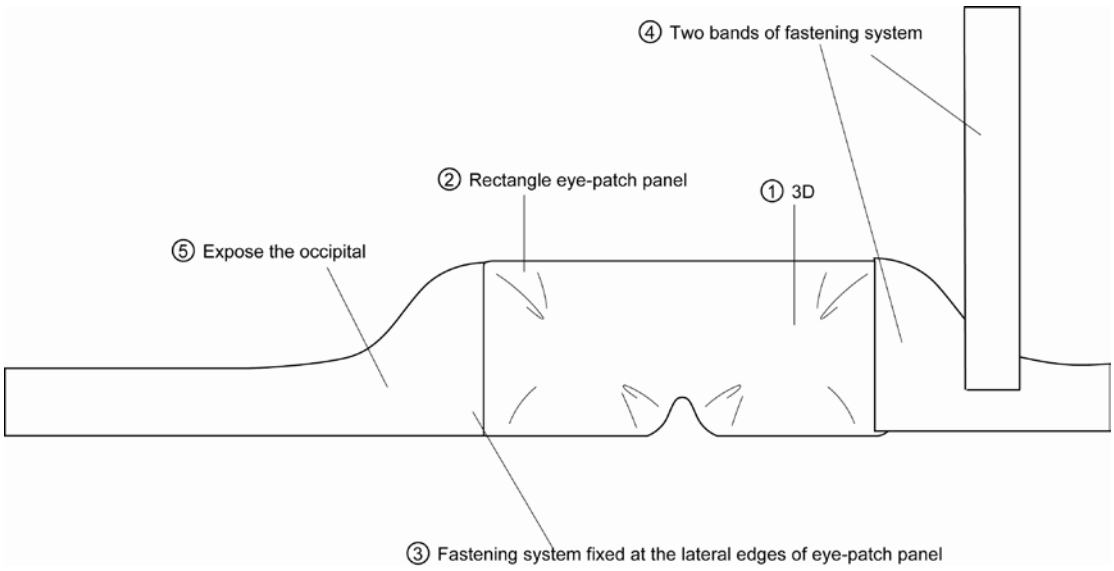


Figure 8-8: The illumination of results of conceptual EP design

8.4 Conclusions

In this chapter, a product development model of protective textile products for

neonates is formulated based on theoretical investigation and practical exploration of design and development of the EP for protecting the neonate's eyes from strong phototherapy light. The product development model with six processes is an extension of Orland's product development process. It organizes a systematic and theoretical framework so as to devise the design and development processes and evaluation criteria of protective clothing for neonates.

Among the processes of this model, conceptual design is the most creative process and is implemented by a strategic-control design methodology. It adopts the technology of the Analysis of Interconnected Decision Areas Model (AIDA) to fully examine the decision space, relate the interdependencies among the available options, determine the compatibility of various design decisions, and assess the final design decision combinations against the specifically functional and other criteria. This design methodology is a valuable tool to balance multiple requirements for protective textile products and to manage the complicated design factors systematically.

The product development model formulates the characteristics of design and development of protective textile products. Therefore, it is able to offer a systematic and theoretical framework of protective product development for neonates.

CHAPTER 9: SUMMARY，CONCLUSIONS，LIMITATIONS AND FUTURE WORK

EPs are routinely used in neonatal units to protect the neonate's eyes from the strong light of phototherapy, which is the most common treatment of neonatal jaundice. A notorious, significant and persistent problem of current EPs is that they may become displaced easily, allowing light to go directly into the neonate's eyes which may remain open even under bright light. The main influences include the moulding of the newborn's head during delivery which makes EPs difficult to be maintained in a secure position and the head movement during phototherapy. Tight binding, however, may cause bruises around the neonate's eyes, compression to the cornea and eyeballs, impairment of drainage of tears, and even infection. Moreover, the level of eye protection by current EPs is somewhat suspicious since phototherapy light may come from various positions. Limited research has been done on light transmission of phototherapy in simulated clinical light conditions. In this research, an EP is developed to provide a comfortable, safe, secure, and reliable eye-patch for comprehensive protection of the neonate's eyes.

9.1 Summary

At the beginning of the research, past studies about physiological mechanisms of EPs, phototherapy treatment, anthropometry of neonates, fabrication and evaluation of

textile materials, and protective textile product design and development were reviewed. The research gaps were identified as (1) anthropometric measurements of the neonate's craniofacial morphology by an appropriate measuring system, (2) fabrication and evaluation of textile materials, (3) evaluation of EP photo-protection in simulated clinical light conditions by appropriate data acquisition instrumentation and (4) a product development model of protective textile products for neonates.

The first task in the research was to explore the design criteria and specifications. A comprehensive exploration of design situations consisted of the hospital environment, the full-term neonates, the phototherapy units and settings, and practical care and treatment by methods of clinical observation and interviews. The weaknesses of the current EPs used in QMH were highlighted by focus group interviews and questionnaire surveys and thereby the design criteria and specifications were established.

The next phase of the research was to measure the anthropometric dimensions of neonates. 14 craniofacial dimensions describing the characteristics of eyes, noses and ears, and 2 head dimensions were identified as the useful dimensions of developing EPs. Craniofacial measurements of 41 neonates were conducted in the SCBU of QMH by a newly developed webcam-based CRP measuring system.

The next step of the research concerned the design and development of EPs. Firstly, a three-layer composite for the eye-patch panel was designed to meet multiple requirements for photo-protection, comfort, safety, aesthetical appearance, and practical use. A Non-woven composite of high elasticity with a hook-and-loop

fastener was determined as materials for the fastening panel to fix the eye-patch panel in an optimum position effectively with great comfort, safety and easy handling. Then a weighting prioritization matrix approach which combines subjective and objective measurements was developed, and evaluations were conducted to select the materials with properties better than those of the current EPs. Based on the obtained anthropometric measurements and selected materials, the style of the EP was designed and related patterns and manufacturing specifications were constructed.

The following step was to evaluate the end-use of the newly developed EP. A wear trial was conducted in QMH to examine six aspects of the EP, including fitting, design and material comfort, security, safety, handling performance, and appearance by the questionnaire survey. The results of the wear trial provided guidelines for further modification. The modified EP was further examined by the clinical wear trial and objective measurement of photo-protection in a simulated clinical light environment assembled by a spectroradiometer, a neoantal head model, a light unit and an incubator until all aspects were accepted by the medical staff and photo-protection of the new EP was better than the current EPs in both aspects of effectiveness and security.

The last phase of the project was to organize a systematic and theoretical framework so as to devise a design and development process and evaluation criteria of protective clothing for neonates.

9.2 Conclusions

It is concluded that EP_n is able to provide comfortable, safe, secure and reliable photo-protection for the neonate's eyes.

The conclusions based on the results of the present investigation are as follows.

(1) The design criteria are photo-protection, comfort, easy handling, disposability, safety, and appearance.

(2) A web camera-based convergent close-range photogrammetric system (CRP) with 1mm accuracy was developed. Other prominent advantages of this measuring method are safety, comfort, minimum interruption, psychological acceptance and cost. Head circumference was determined as a key dimension of the new sizing system. Two sizes of the new sizing system were designed according to the distribution of the neonate's head circufmerence. The measured dimenions were also applied to pattern construction of EP_n and also development of a neonatal head model.

(3) A composite, which comprises an inner layer, a middle layer and an outer layer made of a cotton/ Modal® blended knitted fabric, a cotton woven fabric and a cotton knitted fabric respectively, obtained the highest total weighting index score (combining subjective measurements of handfeel and objective measurements of irradiance, illuminance, air permeability, water vapor transfer, flammability, allergy, weight, and thickness) among the evaluated composites. Its values were higher than those of the composite used for EP_1. The total weighting index score (combining subjective measurements of handfeel and objective measurements of air permeability, water vapor transfer, flammability, allergy, weight, and thickness) of the polyethylene/

polypropylene non-woven elastic composite was higher than that of the elastic material used for EP_2. The total weighting index score of the Velcro hook-and-loop, which was evaluated by subjective assessments and supported by objective measurements, was higher than that of either EP_1 or EP_2.

(4) A prototype of the $EP_{n.v2}$ was designed and developed based on continuous modifications. All aspects, including fitting, design and material comfort, security, safety, handling performance and appearance, were accepted by the medical staff in the clinical wear trial. $EP_{n.v2}$ in an optimum position on a safety threshold gave better photo-protection than EP_1 or EP_2 while $EP_{n.v2}$ had a safety region larger than EP_1 or EP_2. More importantly, the continuous safe photo-protecting period of $EP_{n.v2}$ was significantly longer than that of either EP_1 or EP_2. It is concluded that the newly developed $EP_{n.v2}$ offers more effective and comprehensive photo-protection and is better than current EPs in terms of physical comfort and safety.

(5) A product development model was developed based on an extension of the Orlando's product development theory and modifications of the Analysis of Interconnected Decision Areas Model (AIDA). The product development model attempts to organize a systematic and theoretical framework quantitatively and guide the management of future product development.

9.3 Limitations

A number of limitations are found in the following areas:

(1) Sample size of clinical experiments and questionnaire surveys

All experiments and questionnaire surveys of this research were conducted in the SCBU of QMH. Since the subjects in this study were the neonates in the hospital, the sample size is rather limited. Their health condition must be examined carefully and reviewed periodically so as to reduce any adverse effects and potential dangers or disturbances in the weakest period of their life. Due to the ethics and intense daily medical practice in the hospital, it is also difficult to seek parents' consent and medical staff to research participation.

(2) Anthropometric Measurements

As conditioned by the critical requirements for safety and comfort of neonates, and for the hospital environment, only linear dimensions were measured by the CRP measuring system without projector in the research. This system limits its application to EP design, development and evaluation, and further numerical simulation.

(3) Fabrication and Manufacture of EPs

Material fabrication is one of the most important aspects for developing an EP. Considering the limitations of the research period, budget and resources, all materials for EP_n were purchased from the wholesale market and fabric companies. However, the quality of the fabrics may be difficult to meet the all of photo-protecting and other general requirements for EP developments and for the same reason, traditional technologies were used for manufacture. All this caused a relatively complex manufacturing process and a dis-compact appearance.

(4) External dinical trial

As governed by Hospital Authority, extensive clinical trials are required before the full implementation of a new medical product, particularly if products are used for patients who are unable to give consent.

9.3 Suggestions for Future Work

The major objectives of this research are achieved. However, some further work should be considered to overcome the limitations discussed above. Further research in the following four areas is vital: 1) anthropometric measurements, 2) material fabrication, 3) product development and 4) model application.

(1) Anthropometric Measurements

The photogrammetric measuring system developed in this research has significant advantages in terms of safety and portability. It is suitable to apply the system to protective product development with critical requirements for safety in a complex field condition. Hence, further research can be conducted to improve the function and quality of the measuring system. For example, digital cameras with high resolution can be used to improve the accuracy of measurement and infrared projectors can be assembled to generate 3D profiles of subjects when safety is still guaranteed. It helps not only design an EP but also develop digital 3D human bodies and products and provide a foundation of simulating wear effects of products numerically.

(2) Fabrication of protective products

In this study, several kinds of materials sourced from current market and fabric companies were used for different parts of EP_n to perform different functions. However, they caused potential comfort, manufacture and appearance problems. In future work, materials offering multiple functions to EPs can be developed according to the results obtained in this research. Furthermore, some high-tech materials providing more superior functions, such as smart textiles or nano textiles, can be applied.

(3) EP Development

In this study, an EP prototype was developed by traditional garment-making technologies (such as sewing, pleat technologies). In future work, some new technologies which are more effective for EP development need to be applied. For example, the heat-melted cutting technology can be applied to cutting elastic non-woven fabrics. Thus, the edge of an elastic non-woven fabric can be self-sealed with clean edges without further sewing.

(4) Model Application

The product development model for protective textile product was summarized in this research. As the model generates guidelines on protective product development, it can be applied to a wide range of medical and/or textile products for neonates, like pillows, protective hats, and other neonatal apparel items.

APPENDICES

Appendix 1: The neonate basic information and head morphologic measurements

No.	B1	B2	B3	B4	B5	M1	M2	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14
1	37.40	1	1	2,345	470	324	149	56.7	22.0	19.8	16.6	14.4	11.2	9.5	21.9	22.7	40.8	41.0	24.4	37.9	12.1
2	39.71	4	1	3,250	510	340	174	63.0	25.4	21.3	14.8	16.5	13.5	9.8	22.7	20.7	49.7	49.5	25.5	45.5	11.9
3	40.29	2	1	3,265	510	351	160	55.2	23.3	20.5	16.4	14.3	13.2	10.9	22.7	22.6	46.8	49.2	24.7	46.5	11.4
4	41.71	2	1	4,125	535	367	184	74.4	27.7	22.3	14.3	16.9	12.7	11.9	24.9	23.0	48.9	55.3	29.6	49.9	12.7
5	41.00	7	2	3,825	530	362	180	90.4	26.1	23.3	28.1	19.6	17.5	11.2	35.0	37.0	51.8	54.7	28.5	51.7	10.7
6	39.57	4	1	3,245	515	352	180	69.4	22.8	20.1	13.6	15.4	13.9	13.9	21.6	23.6	45.1	47.9	24.8	45.7	14.9
7	38.57	1	2	3,135	500	355	187	69.6	25.0	18.8	13.3	15.3	13.2	9.6	20.3	20.0	44.8	45.8	25.3	42.1	13.9
8	38.14	2	2	3,065	490	338	170	68.3	22.4	18.1	13.6	16.2	12.7	8.4	22.3	19.2	41.1	46.6	20.3	41.4	7.8
9	38.00	3	1	2,330	475	321	160	53.2	21.7	20.6	14.7	16.5	12.9	12.7	22.7	22.5	45.5	43.2	21.9	43.5	11.6
10	38.71	7	2	3,650	540	354	185	75.4	29.1	17.8	16.0	14.4	11.0	8.5	23.1	22.2	44.2	48.2	28.2	44.4	14.0
11	38.57	0	1	3,755	520	347	235	72.3	27.6	20.1	14.4	16.4	13.5	14.4	22.9	20.7	42.8	45.5	22.9	44.0	10.6
12	38.71	0	1	2,785	490	336	164	68.1	22.6	17.9	16.3	14.1	12.2	8.3	20.1	21.7	43.8	49.1	20.3	43.1	10.8
13	39.29	6	2	3,050	530	339	160	58.1	23.2	20.7	16.2	17.9	15.4	11.0	25.3	23.9	36.4	42.6	25.0	35.7	9.6
14	39.86	1	2	2,653	480	345	155	64.0	25.6	22.4	15.0	16.4	12.5	9.2	23.5	20.8	39.9	43.7	27.2	39.1	12.5
15	37.14	7	1	2,953	500	353	170	68.5	24.5	17.3	14.6	15.4	11.2	10.9	24.0	22.8	42.4	46.7	27.2	40.1	11.4
16	39.14	9	1	2,833	490	335	157	63.3	20.7	19.9	17.1	16.4	13.6	9.9	23.5	23.6	41.4	43.1	23.6	41.2	11.9
17	40.29	5	2	3,218	485	350	170	68.1	24.3	17.7	15.4	15.1	12.5	9.0	23.1	21.8	44.8	46.0	23.7	43.8	13.2
18	37.14	1	2	2,583	480	330	165	65.2	24.7	19.7	15.0	14.1	11.6	9.0	20.7	20.6	43.0	42.1	26.5	38.9	11.5
19	41.14	6	1	3,303	510	358	176	71.3	23.2	22.0	14.5	15.2	13.3	12.2	21.3	21.8	42.2	50.7	28.6	41.6	15.1
20	41.00	6	2	3,563	500	345	164	68.4	21.3	18.1	14.6	14.2	12.7	11.1	21.6	23.3	41.7	44.3	22.6	39.4	10.8
21	41.00	8	1	3,633	480	355	170	70.2	24.9	20.7	16.2	15.2	13.3	12.0	23.8	24.1	49.2	50.6	25.1	48.1	11.6
22	40.86	0	2	3,375	495	349	180	70.6	26.5	19.9	13.6	15.9	13.6	9.6	22.3	20.0	51.9	48.5	28.1	48.5	13.7
23	40.71	0	1	3,240	510	340	168	68.8	23.3	20.5	17.1	15.1	14.9	10.4	23.7	24.3	38.9	41.6	21.4	38.7	8.8
24	37.57	4	2	2,265	440	318	150	62.2	21.0	18.4	15.1	14.0	11.8	9.3	22.0	21.2	36.2	40.8	19.7	37.0	9.5
25	41.00	2	1	2,790	470	320	150	64.8	21.0	18.2	15.8	15.0	11.9	9.8	22.8	20.9	40.6	43.2	25.1	41.1	13.4
26	38.00	4	1	2,785	480	338	165	68.7	24.6	15.8	15.3	15.2	10.6	11.3	23.3	22.2	43.4	43.9	23.0	43.3	11.9
27	39.29	4	2	2,570	465	344	162	64.9	22.8	23.3	15.3	15.1	11.8	9.2	23.2	21.3	45.4	42.5	23.5	42.1	11.9
28	39.14	8	2	3,365	510	356	172	68.4	23.5	24.0	15.2	15.5	13.0	10.3	25.0	22.7	50.8	52.3	27.2	49.5	12.5
29	40.14	0	1	3,735	515	353	184	73.8	24.1	20.1	15.6	12.5	8.8	10.1	24.5	23.6	52.1	50.8	24.8	48.0	11.6
30	37.43	5	2	2,850	470	338	165	66.8	23.5	19.6	21.7	14.4	10.6	9.1	27.8	27.5	39.1	41.4	18.7	37.7	10.9
31	38.57	1	2	3,480	490	344	165	66.0	24.1	17.3	20.8	17.1	13.1	10.2	28.8	27.8	44.6	48.1	23.2	44.3	13.2
32	40.57	1	1	4,495	560	380	190	76.5	27.0	19.3	18.2	16.9	12.0	10.7	29.1	26.0	50.8	50.2	21.0	48.9	9.0
33	39.57	1	1	3,065	490	350	175	71.9	23.3	13.6	14.6	15.8	12.7	9.7	22.8	21.2	42.7	49.3	24.8	45.5	13.1
34	41.14	2	1	3,540	520	365	179	73.7	25.6	17.5	14.2	15.7	12.0	8.7	22.5	19.8	47.4	48.6	27.9	44.5	13.8
35	40.29	6	1	3,400	500	355	175	70.2	23.8	18.9	15.8	16.3	13.9	9.2	25.5	22.2	43.6	49.1	31.2	40.9	12.1
36	39.00	2	1	3,078	470	345	162	71.3	25.0	17.3	17.5	17.6	12.1	10.6	27.9	24.8	41.4	45.4	22.0	42.7	11.0
37	39.57	1	1	3,350	505	335	170	71.7	22.1	17.1	15.0	15.4	12.9	11.0	23.5	21.4	43.2	42.9	20.4	42.3	11.5
38	41.14	10	1	3,863	530	367	170	74.0	24.4	21.2	14.7	16.9	11.5	11.2	24.9	21.1	44.1	47.5	28.7	45.4	12.2
39	38.57	5	1	3,188	510	355	172	68.5	24.8	20.7	19.3	15.9	11.3	8.7	26.5	25.2	47.0	48.7	24.4	42.3	12.5
40	38.43	1	1	3,230	520	357	171	69.2	24.0	19.3	14.1	15.4	12.0	10.4	23.4	21.4	46.6	50.7	25.0	48.1	13.1
41	40.00	0	2	3,570	510	350	170	71.5	25.2	19.9	15.0	16.8	12.7	10.3	23.6	21.4	45.1	47.0	23.1	44.2	13.9

Appendix 2: Correlation of coefficient between each pair of measurements

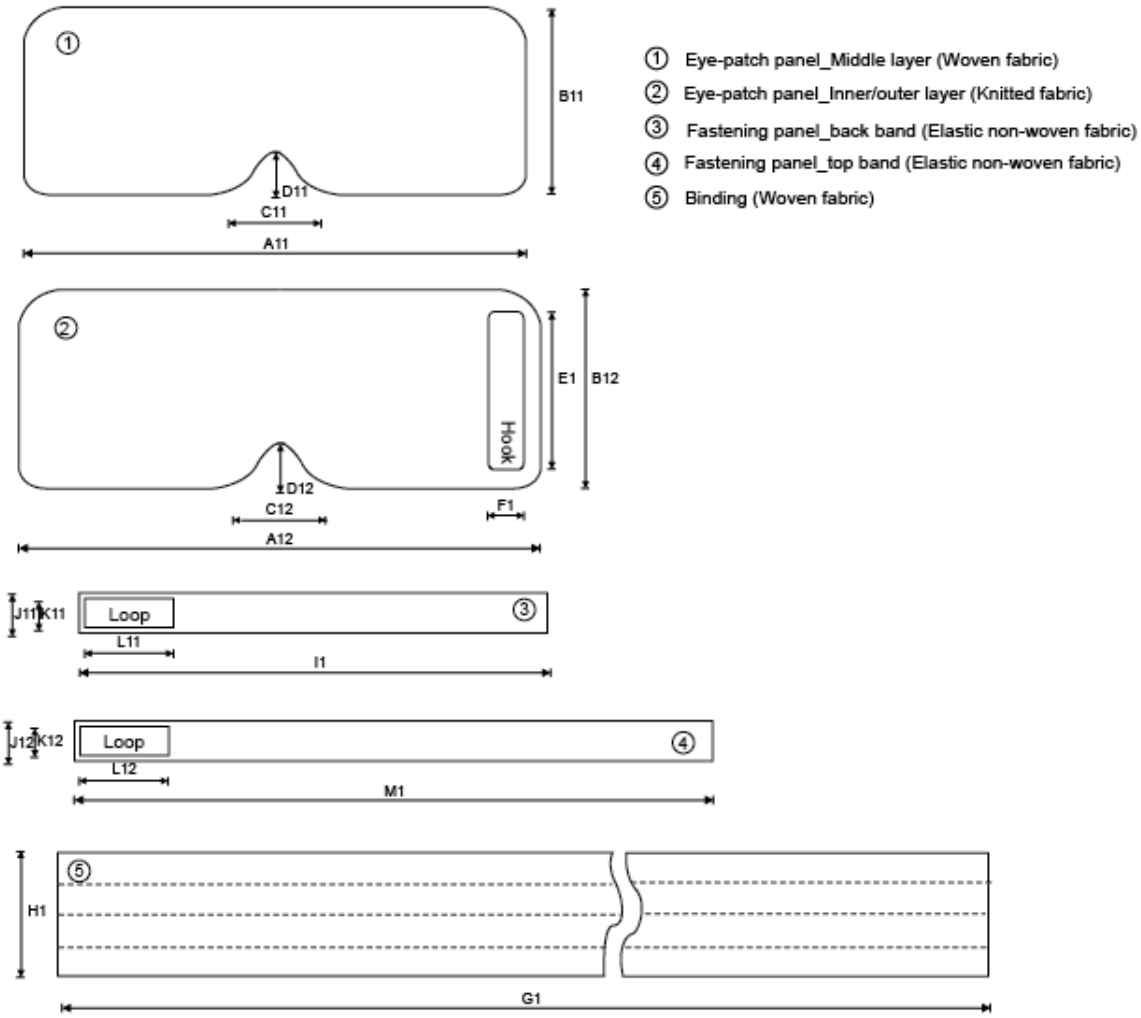
r	B4	B5	M1	M2	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14
B4	1.000	.823(**)	.827(**)	.650(**)	.734(**)	.613(**)	0.131	0.147	.318(*)	0.176	0.293	.421(**)	0.275	.584(**)	.697(**)	.312(*)	.657(**)	0.014
B5	.823(**)	1.000	.756(**)	.595(**)	.555(**)	.572(**)	0.216	0.073	.335(*)	0.240	0.270	0.292	0.203	.465(**)	.608(**)	.388(*)	.511(**)	0.044
M1	.827(**)	.756(**)	1.000	.551(**)	.701(**)	.634(**)	0.204	0.084	0.304	0.091	0.157	.371(*)	0.214	.600(**)	.753(**)	.492(**)	.636(**)	0.184
M2	.650(**)	.595(**)	.551(**)	1.000	.563(**)	.662(**)	0.055	-0.083	0.161	0.123	.406(**)	0.092	0.003	.414(**)	.443(**)	0.196	.457(**)	0.064
P1	.734(**)	.555(**)	.701(**)	.563(**)	1.000	.565(**)	0.018	.365(*)	0.300	0.179	0.109	.505(**)	.435(**)	.496(**)	.636(**)	.310(*)	.607(**)	0.036
P2	.613(**)	.572(**)	.634(**)	.662(**)	.565(**)	1.000	0.128	0.096	0.307	0.011	0.070	0.299	0.118	.482(**)	.499(**)	.431(**)	.489(**)	0.151
P3	0.131	0.216	0.204	0.055	0.018	0.128	1.000	0.185	0.226	.315(*)	0.228	0.215	0.241	.320(*)	0.239	.321(*)	0.225	0.009
P4	0.147	0.073	0.084	-0.083	.365(*)	0.096	0.185	1.000	.390(*)	0.306	-0.079	.846(**)	.932(**)	0.120	0.145	-0.096	0.127	-0.253
P5	.318(*)	.335(*)	0.304	0.161	0.300	0.307	0.226	.390(*)	1.000	.646(**)	0.267	.630(**)	.432(**)	0.124	0.270	0.221	0.255	-0.068
P6	0.176	0.240	0.091	0.123	0.179	0.011	.315(*)	0.306	.646(**)	1.000	.313(*)	0.283	.382(*)	0.032	0.190	0.176	0.132	-0.105
P7	0.293	0.270	0.157	.406(**)	0.109	0.070	0.228	-0.079	0.267	.313(*)	1.000	0.078	0.174	0.107	0.160	0.052	0.272	0.098
P8	.421(**)	0.292	.371(*)	0.092	.505(**)	0.299	0.215	.846(**)	.630(**)	0.283	0.078	1.000	.864(**)	0.274	.331(*)	0.060	.332(*)	-0.251
P9	0.275	0.203	0.214	0.003	.435(**)	0.118	0.241	.932(**)	.432(**)	.382(*)	0.174	.864(**)	1.000	0.214	0.270	-0.027	0.251	-0.205
P10	.584(**)	.465(**)	.600(**)	.414(**)	.496(**)	.482(**)	.320(*)	0.120	0.124	0.032	0.107	0.274	0.214	1.000	.770(**)	.378(*)	.898(**)	0.274
P11	.697(**)	.608(**)	.753(**)	.443(**)	.636(**)	.499(**)	0.239	0.145	0.270	0.190	0.160	.331(*)	0.270	.770(**)	1.000	.529(**)	.843(**)	0.257
P12	.312(*)	.388(*)	.492(**)	0.196	.310(*)	.431(**)	.321(*)	-0.096	0.221	0.176	0.052	0.060	-0.027	.378(*)	.529(**)	1.000	.337(*)	.514(**)
P13	.657(**)	.511(**)	.636(**)	.457(**)	.607(**)	.489(**)	0.225	0.127	0.255	0.132	0.272	.332(*)	0.251	.898(**)	.843(**)	.337(*)	1.000	0.263
P14	0.014	0.044	0.184	0.064	0.036	0.151	0.009	-0.253	-0.068	-0.105	0.098	-0.251	-0.205	0.274	0.257	.514(**)	0.263	1.000
** Corrlation is significant at the 0.01 level (2-tailed)																		
* Corrlation is significant at the 0.05 level (2-tailed)																		

Appendix 3: The fabric objective evaluation results for composite

Indices	C1	C2	C3	C4	C5	C6	EP1
Ev	0.022	0.016	0.014	0.086	0.114	0.104	19.440
E	0.0014	0.0014	0.0014	0.0026	0.0026	0.0024	0.04
AP	2.71	2.71	2.71	2.07	1.84	1.96	0.39
WVT	24.60	24.11	24.53	25.69	25.32	25.45	35.04
F	C-1	C- 1	C-1	C-1	C- 1	C-1	C-1
A	Non	Non	Non	Non	Non	Non	Non
W	420.60	382.20	401.40	480.80	442.40	461.60	365.51
T	1.34	1.27	1.30	1.45	1.42	1.43	3.75

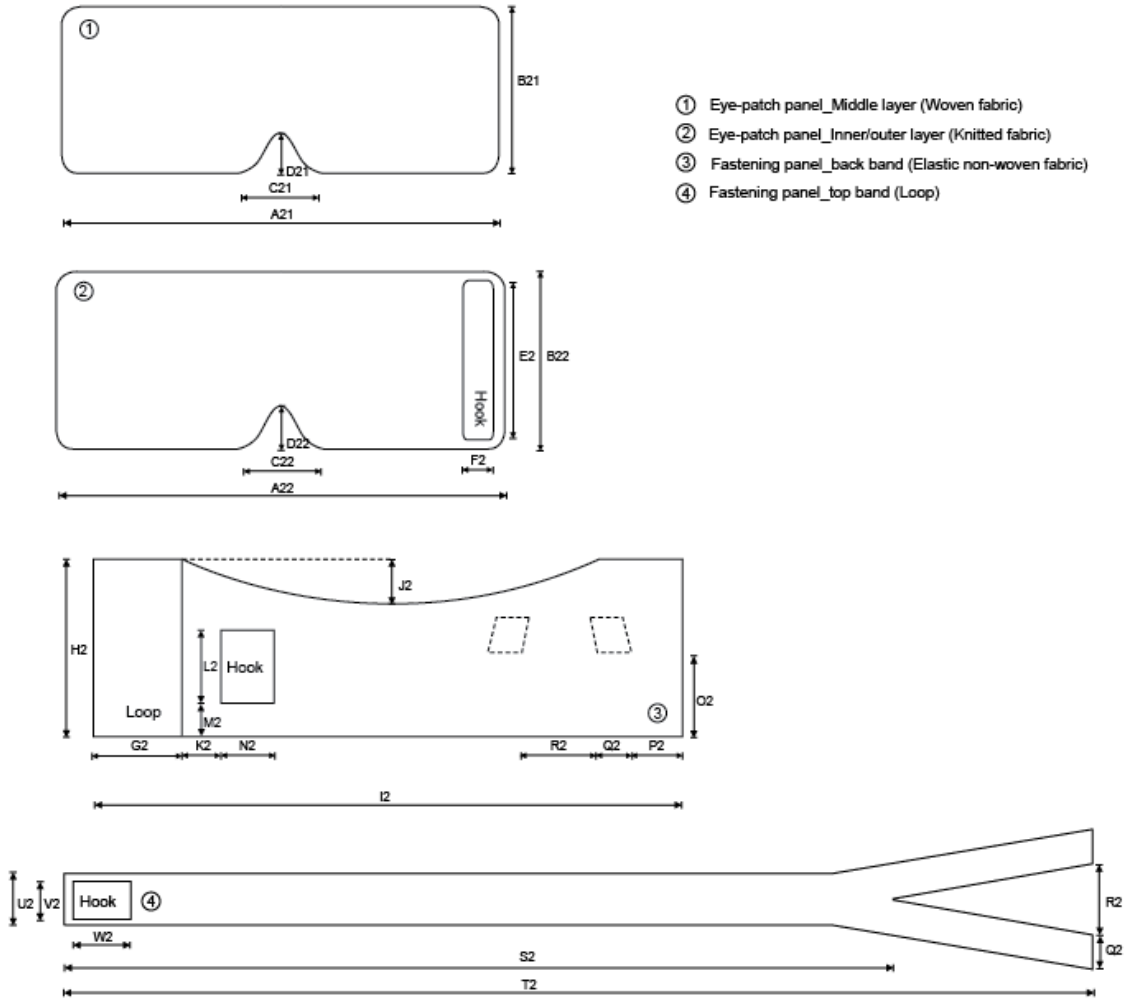
Remarks: Ev: Residual of illuminance (lux); E: Residual of irradiance (µw/cm2/nm);
AR: Air resistance (kpa.s/m); WVT: Water vapor transmission (g/m^2.hr);
F: Flammability (Class 1(C-1)-Class 3 (C-3)); A: Allergy test
W: Weight (g/m^2); T: Thickness (mm)

Appendix 4: Pattern construction for initial style design 1 (small size)



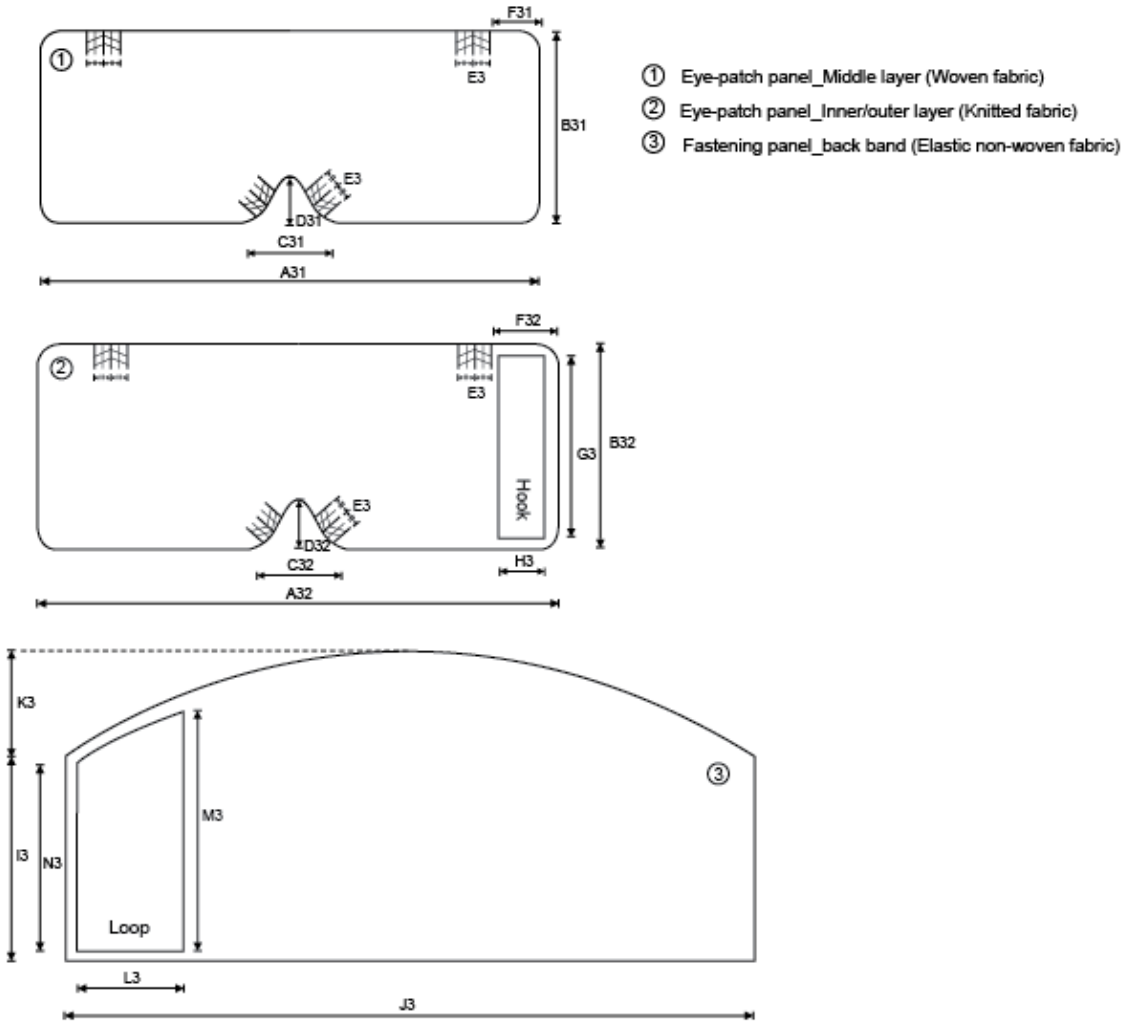
A11 = P1+1/2*(1/2*M1-P1)+5 = 120	F1 = 12
A12 = A11+5 = 125	G1 = 2*A12+2*B12+30 = 390
B11 = (1/2*P3+10)+(P9+8) = 50	H1 = 4*8 = 32
B12 = B11+5 = 55	I1 = 3/4*(M1-A2)/cos θ 2+20 = 180
C11 = P6+7 = 13+7 = 20	J11 = J12 = 15
C12 = C11 = 20	K11 = K12 = J11-5 = 10
D11 = 1/2*(P9+8)+3 = 18	L11 = L12 = 30
D12 = D11 = 18	M1 = 3/4*(M1-A2)/cos θ 1+20 = 180
E1 = B12-15 = 45	

Appendix 5: Pattern construction for initial style design 2 (small size)



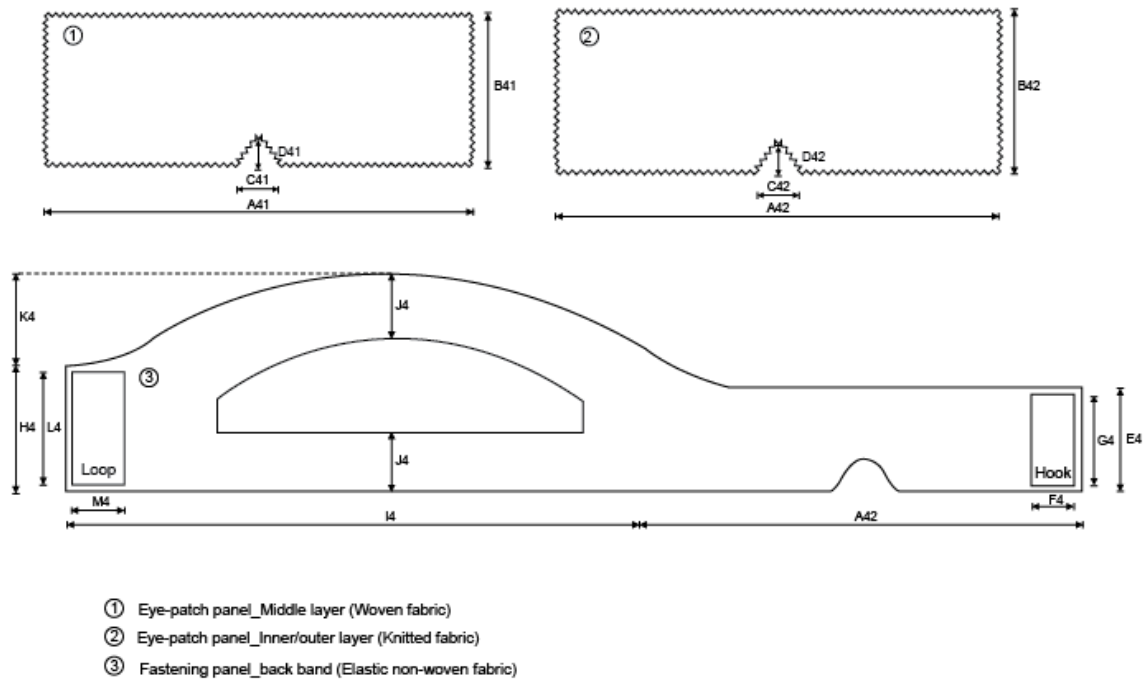
A21 = P1+1/2*(1/2*M1-P1)+5 = 120	K2 = H2-6 = 47
A22 = A21+5 = 125	L2 = G2-5 = 35
B21 = (1/2*P3+10)+(P9+8) = 50	M2 = 12
B22 = B21+5 = 55	N2 = 18
C21= P6+7 = 13+7 = 20	O2 = 20
C22 = C21 = 20	P2 = 1/2*H2 = 28
D21 = 1/2*(P9+8)+3 = 18	Q2 = 3/4*1/2*(M2-A2)+7 = 22
D22 = D21 = 18	R2 = 13
E2 = B22-10 = 45	S2 = 15
F2 = 12	T2 = 60
G2 = 40	U2 = 300
H2 = B22-2 = 53	V2 = 22
I2 = 3/4*(M1-A2) +20 = 180	W2 = V2-4 = 18
J2 = 1/2* B22 = 28	X2 = 25

Appendix 6: Pattern construction for initial style design 3 (small size)



A31 = P1+1/2*(1/2*M1-P1)+5 = 120	F31 = F32 = 47
A32 = A31+5 = 125	G3 = 15
B31 = (1/2*P3+10)+(P9+8) = 50	H3 = B32-2 = 53
B32 = B31+5 = 55	I3 = 3/4*(M1-A32) +20 = 180
C31= P6+2 = 13+2 = 15	J3 = 30
C32 = C31 = 15	K3 = 30
D31 = 1/2*(P9+8)+3 = 18	L3 = M3+12 = 59
D32 = D31 = 18	M3 = I3-6 = 47
E3 = 6	

Appendix 7: Pattern construction for initial style design 4 (small size)



① Eye-patch panel_Middle layer (Woven fabric)
② Eye-patch panel_Inner/outer layer (Knitted fabric)
③ Fastening panel_back band (Elastic non-woven fabric)

A41 = P1+1/2*(1/2*M1-P1)+5 = 120	F4 = 15
A42 = A41+5 = 125	G4 = E4-5 = 30
B41 = (1/2*P3+10)+(P9+8) = 50	H4 = B42-2 = 53
B42 =B11+5 = 55	I4 = 3/4*(M1-A42) +20 = 180
C41 = P6+2 = 13+2 = 15	J4 = 25
C42 = C41 = 15	K4 = 30
D41 = 1/2*(P9+8)+3 = 18	L4 = H4-6 = 47
D42 = D21 = 18	M4 = 20
E4 = A42-20 = 35	

Appendix 8: Neonate information of neonates involved in the first wear trial

No.	Age (day)	Gender	Gestation (week/day)	Weight (g)	Head circumference (mm)
1	7	Male	38/4	2900	329
2	5	Female	38/6	2990	324
3	1	Male	39/1	3580	320
4	1	Male	41	3645	350
5	3	Male	38/6	3805	340
6	1	Female	41	3835	348
7	5	Male	40	3275	325
8	1	Female	39/6	3265	330
9	7	Male	40/6	3775	360
10	1	Female	40/2	3560	355

Appendix 9: Information of neonates involved in the second wear trial

No.	Age (day)	Gender	Gestation (week/day)	Weight (g)	Head circumference (mm)
1	3	Female	41	3508	350
2	4	Male	40	3260	340
3	13	Male	35/4	2740	330
4	5	Female	38/3	3535	360
5	5	Female	41	3060	340
6	5	Male	38/2	2965	335
7	10	Female	39	3140	320
8	6	Female	41/1	3670	351
9	3	Male	40/3	2840	330
10	5	Male	40/3	2725	310

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