

Design of a Device to Provide  
Visual Stimulation to Infants  
Confined in Incubators

by

Anna Marshall-Baker

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APPROVED:

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Dr. J.E. Bowker, Chairman

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Dr. J. McLain-Kark

-----  
Dr. J. Sawyers

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Dr. P. S. Zeskind

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TO INFANTS CONFINED IN INCUBATORS

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Committee Chairman: Jeanette T. Bowker  
Housing, Interior Design, and Resource Management

(ABSTRACT)

The purpose of this study was to examine the effects of providing stationary and nonstationary visual stimuli to preterm infants by designing a device that met basic hospital safety requirements and fit within the incubator. A sample of 20 preterm infants were observed. Differences in responses between baseline, stationary, and nonstationary conditions were recorded using state, focal point, time attending, heart and respiratory rates. Each infant was observed on two separate days. Each observation period was divided into three 2-minute segments. On the intervention day, data were collected in a baseline, stimulus, stimulus sequence. On the nonintervention day, only baseline data were collected in the three 2-minute time segments. Parametric and nonparametric analyses revealed significant differences in state, focal point, and heart rate between observation days. Results of state, focal point, and heart rate indicate a response to the stimulus during the first stimulus exposure period. Significant effects in state, focal point, time, and heart

rate during the second exposure period indicate an orienting response. It is suggested that after a period of response and reorganization, the infants were able to orient to the device during the second exposure period. These results also suggest that this visual stimulation device may be helpful in long-term visual stimulation studies and interventions.

## DEDICATION

This paper is dedicated to Alden who, at age 3, represents the hope of parents of preterm infants - to bring children through neonatal intensive care and into a cycle of normal development.

## ACKNOWLEDGEMENTS

Forever etched in my mind are the name and face of my first subject, N\_\_\_\_ L\_\_\_\_. She helped me through the initial trial with an enthusiastic response, and provided me the encouragement and incentive necessary to continue this project. I am grateful to her and to all the infants who participated in the study. I appreciate the trust of their parents, and the support and cooperation of the NICU staff at Roanoke Memorial Hospital.

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## I. The Problem and Its Setting

### Introduction

Approximately 10% of the infants born in the United States are born preterm, before 37 weeks gestational age (Werthmann, 1981). The period between their birth and due date can be viewed as a lag in the overall maturation of the preterm infant's central nervous system (Korner, 1981). Even those preterm infants who are considered at low risk for developmental delays accumulate auditory and visual deficits during this period that may negatively affect their cognitive development (Friedman, Jacobs, & Werthmann, 1981). The present design of incubators which house these infants, frequently for extended periods of time, increases the odds for survival by providing a controlled environment; however, the quality of their lives depends not just on physiological recovery, but on adequate development of cognitive and social-emotional behaviors. One obstacle in meeting the goal of optimal development in these areas is knowing how best to facilitate the normal maturation of the infant's central nervous system. Korner (1981) suggests that rather than concentrate efforts on the amelioration of individual sensory function, intervention programs should address the overall development of the infant's central nervous system. Before an integrative intervention program can be initiated, means of facilitating optimal development for each specific sensory

function are necessary.

Numerous studies provide evidence that tactile-kinesthetic and auditory stimulation facilitate development of preterm infants. The effects of visual stimulation on the developing infant have not been researched; however, a number of studies investigating the visual capabilities of preterm infants have been conducted. Evidence indicates that preterm infants approximately 30 weeks gestational age are capable of focusing on a visual target. Infants 31-32 weeks gestational age evidence tracking, visual preference, and fixation. Fully mature visual orientation patterns have been observed at 33-34 weeks gestational age (Dubowitz, Dubowitz, Morante, & Verghote, 1980; Hack, Muszynski, & Miranda, 1981). Preterm infants averaging 35 weeks gestational age demonstrate visual recognition memory when presented with novel or familiar visual stimuli, indicating that the preterm infant has the capability to respond discriminately to visual information (Miranda, 1970; Werner & Siqueland, 1978). Because the central regions of the retina are immature at birth, full-term infants are thought to first notice motion through peripheral vision and scanning techniques (Banks & Salapatek, 1983; Sokol & Jones, 1979). McKenzie and Day (1976) investigated infant's attention to stationary and nonstationary visual stimuli, and conclude that a nonstationary visual stimulus elicits more attention than a stationary stimulus.

Preterm infants are not exposed to controlled, systematic visual stimulation. The purpose of this study was to investigate the possibility of providing stationary and nonstationary visual stimuli to infants confined in incubators. Using existing knowledge of visual acuity in preterm and full-term infants, a device was designed that housed the stimulus and could be placed next to the infants. The design of this device may become the instrument necessary to eventually evaluate long-term effects of visual stimulation.

#### The Objectives

The objectives of the study were:

1. To design a device that would fit within the incubator and not interfere with the infant or attending adults, and that would meet basic hospital safety requirements, i.e., stability, visual unobtrusiveness, and capability to be sterilized.
2. To create a visual stimulus.
3. To observe the visual stimulus in stationary or nonstationary modes.
4. To evaluate the effect the device had on preterm infants confined in incubators using five independent measures: heart and respiratory rates, state of arousal, focal point, and total length of time the infant attended the visual stimulus.

## The Hypotheses

The hypotheses of the study were:

1. There would be a significant difference between baseline and stationary mode heart rate activity.
2. There would be a significant difference between baseline and nonstationary mode heart rate activity.
3. There would be a significant difference between stationary and nonstationary mode heart rate activity.
4. There would be a significant difference between baseline and stationary mode respiratory activity.
5. There would be a significant difference between baseline and nonstationary mode respiratory activity.
6. There would be a significant difference between stationary and nonstationary mode respiratory activity.
7. There would be a significant difference between baseline and stationary mode state of arousal.
8. There would be a significant difference between baseline and nonstationary mode state of arousal.
9. There would be a significant difference between stationary and nonstationary mode state of arousal.
10. There would be a significant difference between baseline and stationary mode focal point.
11. There would be a significant difference between baseline and nonstationary mode focal point.
12. There would be a significant difference between stationary and nonstationary mode focal point.

13. There would be a significant difference between stationary and nonstationary mode total length of time attending the visual stimulus.

#### The Limitations of the Study

The study was limited to preterm infants in the intermediate area of the Neonatal Intensive Care Unit at Roanoke Memorial Hospital.

The study was limited to preterm infants 34-37 weeks gestational age which was determined by the Dubowitz examination of physical and neuromuscular development.

The study was limited to preterm infants who were attached to ECG/respiratory monitors.

The study was limited to preterm infants not exhibiting serious behavioral, neurophysiological, or maturational problems.

The study was limited to those preterm infants whose parent(s) consented to the research.

#### The Theoretical Framework

There is evidence that intervention and interaction with the environment can positively affect the development of infants born at risk. An appropriate model for intervention programs has been proposed by Sameroff and Chandler (1975). The transactional model of development is based upon the bidirectionality that exists between organism and environ-

ment. That is, the environment provides a stimulus input which facilitates the development of the organism, enabling the organism to interact with the environment at a higher cortical level. The succeeding stimulus input possesses a different degree of complexity, meeting the new physiological capabilities of the organism and challenging it to develop further. A cyclic pattern is created: a change in the environment produces a change in the organism which elicits a change in the environment.

The advantage of this transactional model of development is the bidirectional relationship between the environment and the organism. In support of this model are studies by Zeskind and Ramey (1978; 1981). By manipulating the environment, the detrimental effects of fetal malnutrition were ameliorated. Other studies based upon the transactional model of development have concentrated on the effectiveness of intervention programs which facilitate the mother's positive perception of her child. A more positive perception is one element in a cyclic effect: positive perception (parent education, for example) encourages interaction with the child which supports the mother's perception which encourages interaction (Ainsworth & Bell, 1974; Field, Dempsey, Hallock, & Sherman, 1978; Minde, Trehaub, Corte, Boukydis, Celhoffer, & Marton, 1978; Whitt & Casey, 1982; Widmayer & Field, 1980; Worobey & Belsky, 1982; Zeskind & Iacino, 1984). In each case, the environment (mother) has been manipulated in some way to

facilitate the child's development. Similarly, this study is based on the transactional model of development: designing a device that will house a visual stimulus (change in the environment) and possibly become the tool required to measure long-term effects (changes in development) due to visual stimulation.

#### Justification for the Study

Although some of the capabilities of the preterm infant are known, more information is needed to develop intervention programs which address the overall maturation of the preterm infant's central nervous system (see Korner 1981). Long-term intervention programs and later developmental assessment provide evidence that intervention programs can facilitate the infant's development. A planned program of visual stimulation has not been initiated to date. The design of the device proposed in this research will provide the means necessary to investigate a controlled program of visual stimulation. The mobile device could be placed in the incubator and left unattended, and could become a permanent feature. The visual stimulus could be altered to suit the individual needs of the occupant. The variable speed motor would enable the visual stimulus to be observed at different speeds, and could operate for varying lengths of time during different times of the day. In addition, the device could be modified to accommodate auditory and visual

stimuli. The success of the design, altering the infant's environment and capturing his/her attention, is the first step toward acquiring information necessary to initiate an effective visual stimulation program.

## II. The Review of Literature

Concern with the preterm infant has not just become an issue during the 20th century. Hippocrates, in 470 B.C., stated that, "No fetus coming into the world before the seventh month of pregnancy can be saved" (Hess, 1922, p. 205). In Paris in 1881, a device built to incubate chicken eggs was adapted for human occupancy and installed at the local maternity hospital. In 1915, a bassinet with three copper walls was designed to house preterm infants. The space between two of the three walls was filled with water. An adjacent space was filled with thermal insulation. The water was heated which warmed the infant's chamber through conduction and convection. Except for a small opening over the infant's head to allow observation and fresh air access, the copper cover enclosed the infant chamber completely. As the need for oxygen therapy became apparent, this design was altered in such a way that the cover could be closed tightly, enclosing the infant entirely. After World War II, a manufacturer of acrylic cockpits for fighter aircraft introduced an incubator design which became the industry standard, and, with some variation, remains so to this day (Lundeen & Kunstadler, 1958). The acrylic enclosure allows continuous visibility of the infant, as well as controlling airborne bacteria, temperature, humidity, and supplemental oxygen. Portholes and a door in one panel allow access to the infant

who rests on a mattress. The portholes provide a means to attach the infant to medical equipment: intravenous therapy lines, supplemental oxygen, or wires which lead to a device that monitors temperature, heart and respiratory activity.

Though incubators increase the odds of survival by providing a controlled environment, this isolation limits the infant's exposure to elements of the normal environment. At issue is not whether the infant is provided any form of stimulation in this environment, incubator and Neonatal Intensive Care Unit (NICU), but if the available stimulation is of a quality that will enhance the infant's development. Brazelton (1982) cautions that unless the interactive processes between each infant and his environment are understood, the environment's appropriate role in enhancing the infant's recovery may not be realized. In fact, oversimplified, nonindividuated intervention programs may be detrimental. Intervention programs have previously been based on the assumption that preterm infants experience sensory deprivation and that increased environmental stimulation would be beneficial. After searching for the basis of this assumption, Cornell and Gottfried (1976) concluded that there was no firm evidence to support it. In a later study, Gottfried et al. (1981) determined that although infants in the intensive care unit environment did not lack for auditory, visual, or tactile stimulation, they experienced relatively little inte-

grated sensory experiences. A description of the special care unit concluded that preterm infants received large amounts of ongoing stimulation, in fact, continuous exposure to cool-white fluorescent lighting and frequently to high sound levels (Gottfried, Hodgman, & Brown, 1984). Lawson, Daum, and Turkewitz (1977) state also that preterm infants in a NICU are exposed to excessive environmental stimulation. In addition to continuous exposure to relatively unchanging patterns of stimulation, the rhythms of the day, the opening of the morning and the closing of the day, are missing from the NICU environment. This diurnal rhythmicity is considered by some to be essential to the growth and development of the human organism. Lawson et al. conclude that preterm infants suffer from patterns of stimulation which are inappropriate and may actually be detrimental to their sensory integration. Gottfried et al. (1984) conclude that NICUs are, for the most part, nonsocial environments for the newborn occupants. There is little organization of physical and social stimulation incorporated into the recovery program for the infants. On an average, the preterm infant experiences eight minutes of contact per hour, and, frequently, this contact produces discomfort (Marton, Dawson, & Minde, 1980).

#### Tactile and Auditory Stimulation Programs

Long-term intervention programs suggest that the environment can have a positive effect on the development of

preterm infants. Research concentrating in this area has dealt primarily with the mother-infant dyad and the effect of that relationship on the infant's later abilities, including cognitive skills. A number of studies have investigated the effectiveness of an intervention program directed at the mother which facilitates her perception of her child. As discussed previously, a more positive perception is one element in a cyclic effect: positive perception encourages interaction which supports perception which in turn encourages interaction (Field, Dempsey, Hallock, & Sherman, 1978; Minde, Trehaub, Corte, Boukydis, Celhoffer, & Marton, 1978; Whitt & Casey, 1982; Widmayer & Field, 1980; Worobey & Bel-sky, 1982; Zeskind & Iacino, 1984). Preterm infants who have been recipients of increased interaction with their mothers evidence significant gains in their maturational development. Rice (1977) introduced mothers of preterm infants to a program of tactile-kinesthetic stimulation. When assessed for maturational development at four months of age, the infants who had received the tactile-kinesthetic stimulation exhibited greater neurological and mental development, and gained weight at a faster rate than a group of infants not participating in the program of stimulation. The raw data indicated a trend in the positive direction for performance on the Bayley Scales of Infant Development, though no significant difference was reported.

Scarr-Salapatek and Williams (1973) instructed the

nursing staff in a visual, tactile, and kinesthetic stimulation program. Low-birth-weight infants were rocked, talked to, and handled affectionately. Nursery birds from a mobile were attached inside the incubators for these same infants. Treatment continued throughout the first year as weekly home visits were arranged for the experimental group. A social worker provided instructions and demonstrations of stimulating child care, appropriate games, as well as books, posters, and other simple toys. When assessed at four weeks of age, the experimental group evidenced significant advantages in addition to greater weight gain than a control group who received typical pediatric care. At 1 year of age, the experimental group evidenced significantly higher development quotients, with an average of 10 points separating the two groups. The intervention treatment had elevated the experimental group to approximately normal levels of behavioral development.

In a similar study conducted by Powell (1974), low-birth-weight infants were placed in one of three groups: 1) infants who received extra stimulation from the hospital staff; 2) mothers allowed to handle their infants in the hospital; 3) infants who received treatment typical of a preterm nursery. Findings of follow-up exams indicated that there were no significant differences between the two groups of stimulated infants, even though one group experienced increased interaction with their mothers and the other group

received minimally increased amounts of stimulation from members of the hospital staff. The performance scores for both experimental groups were higher than those of the control group.

The evidence is convincing that intervention and interaction with the environment can positively affect the development of infants born at risk. Longitudinal auditory studies provide additional support for this conclusion.

Though a fetus or preterm infant 25-26 weeks gestational age may evidence responses to sound, these responses are inconsistent. There is some question concerning when the auditory system becomes functional in the human organism (Parmelee, 1981). Evidence has been assembled that preterm infants 28 to 32 weeks gestational age achieve greater developmental maturation, motor and tactile-adaptive, and greater auditory and visual abilities when subjected to auditory stimulation alone, or auditory stimulation in combination with rocking beds or oscillating waterbeds. Auditory stimulation consisted of heartbeat, intrauterine sounds or a tape recording of the mother's voice (Katz, 1971; Burns, Deddish, Burns, & Hatcher, 1983). Barnard (1974) found that preterm infants 32-33 weeks gestational age provided with rocking beds in their incubators and tapes of intrauterine sounds developed longer and more quiet sleep during the first few days of postnatal life. These infants also exhibited more rapid neurological development. Barnard suggests that the

beneficial effects of more frequent and extended periods of quiet sleep would facilitate the neurophysiological maturation of the infant. As Scarr-Salapatek and Williams (1973) suggest, it seems likely that the sensory systems would change in response to their experience in the extrauterine environment, as the other systems, respiratory and digestive, alter their functioning processes to adapt to extrauterine life.

### Visual Acuity

Animal studies have indicated that lack of various forms of stimulation detrimentally affect brain growth. The nerve fibers which carry information to the brain grow thicker and transmit messages quicker as a result of exercise via stimulus inputs (Bower, 1977; Parmelee & Sigman, 1983). Deprivation of visual experiences negatively affects the development of the visual system. Kittens deprived of sight in one eye from birth to age 2-3 months, evidenced profoundly defective vision in the eye deprived of visual stimulus inputs, though the pupillary light reflexes were normal (Wiesel & Hubel, 1963). A similar study by Sherk and Stryker (1976) supports these findings. The neurons of kittens raised in altered environments, environments which consisted of vertical or horizontal stripes, were oriented around a vertical or horizontal axis of the visual cortex, respective of the kitten's particular environment. Upon return to a normal environment

after age 5 months, the visual cortex did seem to adjust somewhat, attesting to the plasticity of the visual system, though the kittens remained clumsy and frequently walked into table legs and other vertical obstacles (Blakemore & Cooper, 1970). In a study by Mitchell, Freeman, Millodot, and Haegerstrom (1973), human adults whose vision had been optically corrected for astigmatism since childhood were examined. Astigmatism is a visual defect which results when the rays from a particular contour fail to meet in a focal point, resulting in blurred vision. Mitchell et al. found a reduced acuity of the neural origin that does not fully recover after optical correction. They conclude that early abnormal visual experience results in corresponding neural alterations.

Physiologically, in the preterm infant, apical dendrites begin to branch shortly after 30 weeks gestational age. By 34 to 36 weeks gestational age, basilar dendrites exist in significant numbers and size. There is evidence that environmental stimulation can facilitate the growth of these nerve fibers which carry information to and from the brain (Wiesel & Hubel, 1963; Blakemore & Cooper, 1970; Sherk & Stryker, 1976; Parmelee & Sigman, 1983). Because of the unique characteristics of development in each individual, comparisons of the ontogeny of nerve fiber growth in infants is difficult. Though the necessary physiological architecture may be present, younger preterm infants, less than 35 weeks conceptional age, may not possess the neurological maturity neces-

sary to process visual information (Rose, 1980; Sigueland, 1981; Parmelee & Sigman, 1983). Preterm infants assessed at 40 weeks gestational age exhibited longer durations of visual fixation suggesting either an inability to inhibit or modulate responses, or a lag in processing the visual information (Sigman, Kopp, Litmann, & Parmelee, 1977).

When visual fixation techniques are used, preterm infants evidence degrees of alertness that increase steadily between 31 to 36 weeks conceptional age. Though the initial periods of quiet awakeness are brief, those infants between 31-34 weeks conceptional age may be ready to experience their first degrees of interaction with the environment (Hack, Miranda, & Fantz, 1975; Hack, Mostow, & Miranda, 1976). In some preterm infants, pattern fixation has been observed as early as 30 weeks gestational age, thus providing evidence that the human brain may be capable of waking states as much as 10 weeks before term (Hack, Muszynski, & Miranda, 1981). Dubowitz, Dubowitz, Morante, and Verghote (1981) found that preterm infants less than 30 weeks gestational age were only capable of focusing on a visual target, while infants 31-32 weeks gestational age evidenced tracking, visual preference, and fixation. Fully mature visual orientation patterns were observed at 33-34 weeks gestational age. Preterm infants averaging 35 weeks gestational age demonstrated visual recognition memory when presented with novel or familiar stimuli, indicating that the preterm infant has the capability to

respond discriminately to visual information (Miranda, 1970; Werner & Siqueland, 1978).

Visual pattern preferences for preterm infants approximately 35 weeks gestational age have been identified. In each study, the infants were placed in a testing chamber separate from their incubator. Miranda (1970; 1976) used flat visual patterns that were grouped by acuity (black stripes or a gray square), complexity (different number of small squares), linear-round (various bars or circles), and other variations (abstract patterns, stylized or realistic face, checkerboard pattern). Using the corneal reflection technique, Miranda concluded that preterm infants approximately 35 weeks gestational age preferred 1/4" stripes. Dubowitz et al. (1980) used a similar testing procedure. Four pairs of patterns were used: 1) black and white stripes versus gray square; 2) four black squares versus four gray squares; 3) two 1" black squares versus two 2" black squares; 4) two 1" black squares versus eight 1" black squares. Preterm infants 30-34 weeks gestational age consistently preferred the black and white stripes or the four black squares.

In full-term infants, the central retinal regions are not mature at birth. Infants are thought to first notice motion through peripheral vision and scanning techniques (Banks & Salapatek, 1983; Sokol & Jones, 1979). McKenzie and Day (1976) found that full-term infants 9 weeks old look longer at a visual stimulus than 16 week old infants whether

the stimulus is stationary or nonstationary. A possible explanation is that the older infants would have preferred a more complex visual pattern. In both groups, however, a non-stationary visual stimulus elicited more attention than a stationary stimulus.

Tactile and auditory intervention programs have facilitated development of infants born at risk. A number of studies have been conducted exploring the visual capabilities and pattern preferences of preterm infants. In order to research effects of visual stimulation on the development of preterm infants, an established procedure is necessary. The development of the proposed research device that would provide a visual stimulus with some variability would contribute to the first step in establishing this procedure.

### III. Methodology

#### Subjects

Twenty subjects were observed in the NICU at Roanoke Memorial Hospital. The NICU has two distinct areas. Neonates whose medical conditions are more critical are housed in one room of the unit. Infants whose medical conditions are more stable are housed in a separate room. Infants participating in this study were observed in the less critical room of the NICU. Lighting within the unit consisted of fluorescent tube lighting typical of commercial buildings, schools, and hospitals. Two small windows at one end of the room provided a minimal amount of natural light. The incubators and cribs were arranged around the room periphery. Under more crowded conditions, some incubators and cribs were located in the center of the room. The incubators and cribs were rearranged frequently. The unit included necessary medical and monitoring equipment, rocking chairs, three sinks, and a central station for bathing and performing minor medical procedures. Entry into the unit was possible through any of three doors.

Each preterm infant's gestational age at birth was determined by the NICU staff using the Dubowitz Exam (Dubowitz, Dubowitz, & Goldberg, 1970). This procedure examines neuromuscular and physical maturity which is used to estimate the length of time in weeks between conception and birth. The gestational age of the subjects ranged from 27 to 36 weeks

and averaged  $31.7 \pm 2.6$  weeks. The conceptional age of each infant was determined by adding the number of weeks between birth and date of the observation day to the estimated gestational age. The conceptional age of the infants ranged from 29 to 38 weeks, and averaged  $34.1 \pm 1.96$  weeks.

Of the sample of infants observed, 10 were male and 16 were white. One infant had a white mother and black father. The remaining three infants were black. A summary of characteristics of the sample is presented in Table 1.

Infants exhibiting evidence of serious behavioral or neurophysical problems were not considered for this study. Though originally intended to exclude infants from the study who were undergoing chemical therapy for treatment of erratic heart rate activity, availability of subjects became an issue. Consequently, infants receiving theophylline, a chemical used to facilitate beat to beat regularity, were included in the sample. Of the 20 subjects in the sample, 10 were undergoing theophylline treatments. Five of those 10 were observed in Order 1. The remaining 5 were observed in Order 2 (see page 33).

Each infant was included in the study only after parental consent was obtained. Each infant's heart and respiratory activity was being monitored, making it possible to take readings from digital or dial displays.

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Table 1. Characteristics of the 20 Subjects.

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N=20

Chemical therapy: 10

Sex: Males: 10 Females: 10

Race: White: 16 Other: 4

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Measure	Mean	Standard Deviation
Birthweight (grams)	1479.35	324.45
Testweight (grams)	1557.95	270.76
Birth (gestational) age (weeks)	31.74	2.59
Test (conceptional) age (weeks)	34.03	1.96

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### Design\_of\_the\_Device

The visual stimulation device, constructed primarily of 1/8" clear acrylic, was designed to meet the minimal space restrictions of the Air-Shields Isolette, one of three different types of infant incubators used in the NICU at Roanoke Memorial Hospital. A 1/4" acrylic panel hinged to the back of the device slid underneath the mattress, supporting the device by resting on the floor of the incubator in the Ohio Med Servo-Care units and Ohio IC Incubators, and by resting on a tray in the Air-Shields Isolettes. To accommodate the depth of the infant's mattress, the distance from the hinged panel to the underside of the rectangular box which housed the visual stimulus was 1" (see Figure 1). In the case of the Air-Shields Isolette, the back of the device rested between the portholes, a width of 7". Height was not a restricting factor in any of the incubators. Each of the three different models provided more space than necessary to accommodate the size of the device. The overall dimensions of the device were 6-1/8" X 6-3/4" X 2". A piano hinge connected back and base, allowing the base to rotate flat against the back to facilitate packing and transporting. The piano hinge had a maximum rotation of 270°. The 1/4" back and base were angled to 45° to accommodate the piano hinge. A second piano hinge attached the front cover to the device and allowed manipulation of the enclosed stimulus. Magnetic clips secured the cover on each side (see Figure 2). All

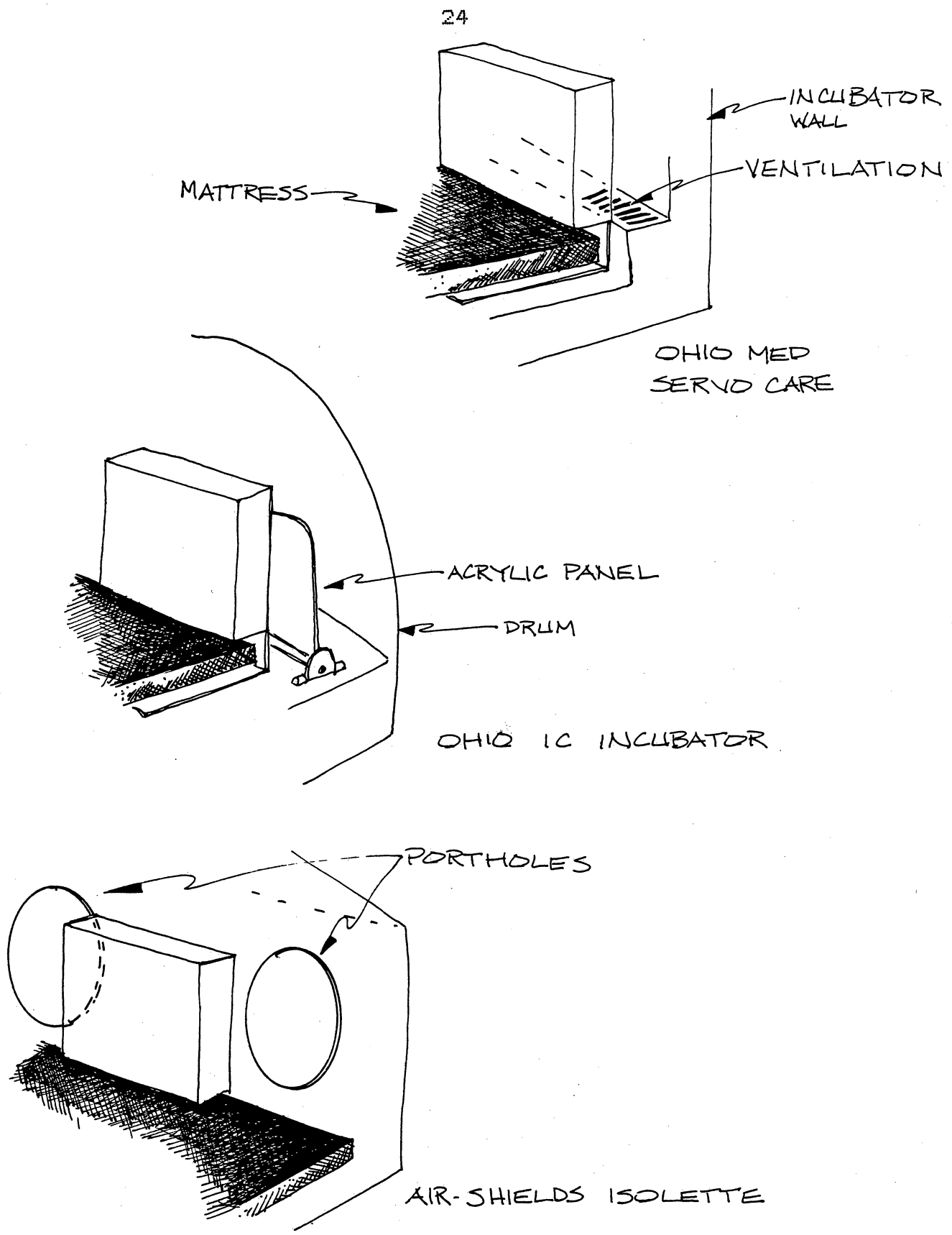


Figure 1. Design of the Device: Spatial Limitations

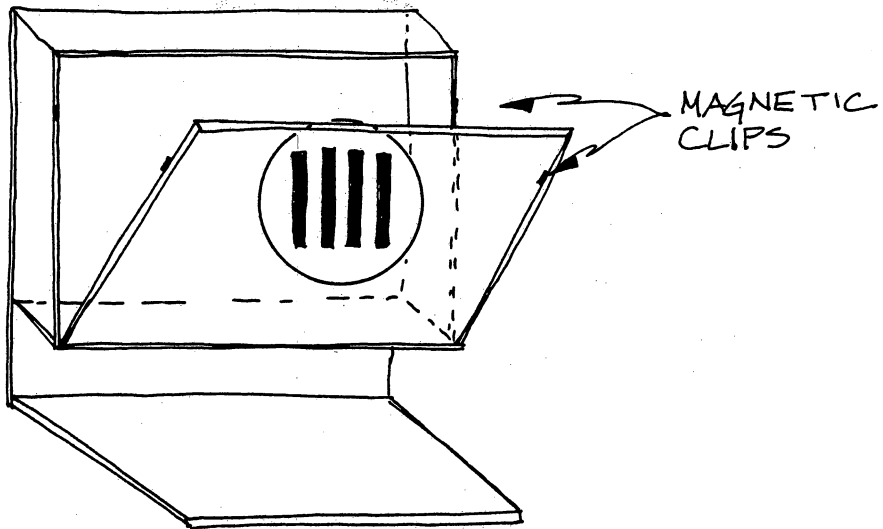
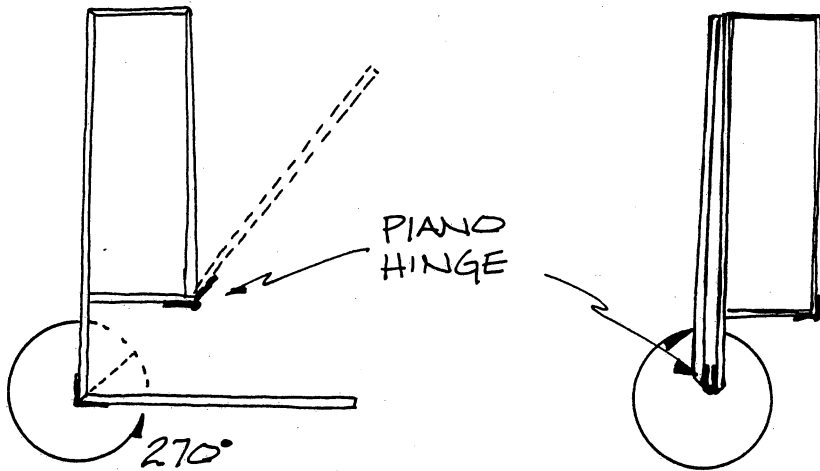


Figure 2. Design Detail: Base and Cover

seams were glued with an acrylic solvent. The box was placed in an oven overnight and heated to evaporate any residue. All edges and corners exposed to the infant were burnished and polished.

A pattern of 1/4" black stripes, recognized as a preferred pattern of preterm infants approximately 35 weeks gestational age (Dubowitz, Dubowitz, Morante, & Verghote, 1980; Miranda, 1970; 1976) was selected as the visual stimulus for both stationary and nonstationary modes. The 4-1/2" squares and 4" X 8" rectangles used by Miranda (1970; 1976) and Fantz and Fagan (1975), respectively, in visual attention studies with high risk infants, were modified. Use of a 4", translucent white acrylic disc eliminated the 90° corners of the square which would have created an interest in themselves as they rotated. The surface of the disc was chemically etched to produce a matte finish and control confounding reflections. Chartpak 1/4" black matte craft tape was applied to the disc to assure uniformity of the stripes. The stripes were spaced 1/4" apart.

As the infant lay near the side of the incubator opposite the panel opening, the distance from his eyes to the visual stimulus was approximately 19 cm. (7"), the distance at which a newborn infant can focus on a visual target (Dubowitz, Dubowitz, Morante, & Verghote, 1980; Friedman, Jacobs, & Werthmann, 1981).

The depth of the device was 2" to accommodate a perma-

ment magnet direct current motor. A gear ratio of 10 to 1 allowed the shaft of the motor to rotate 10 times for every 1 rotation of the 3-1/2" visual stimulus which was attached to a gear. The disc (visual stimulus) rotated 1 cycle per 2 seconds (Kaufmann, Stucki, Kaufmann-Hayoz, 1985; McKenzie & Day, 1976). The power supply was a 1-1/2 volt battery placed outside the incubator. The device was wired through one side with a banana plug. A switch on the power supply enabled the experimenter to precisely control the stationary and nonstationary observation periods (see Figure 3).

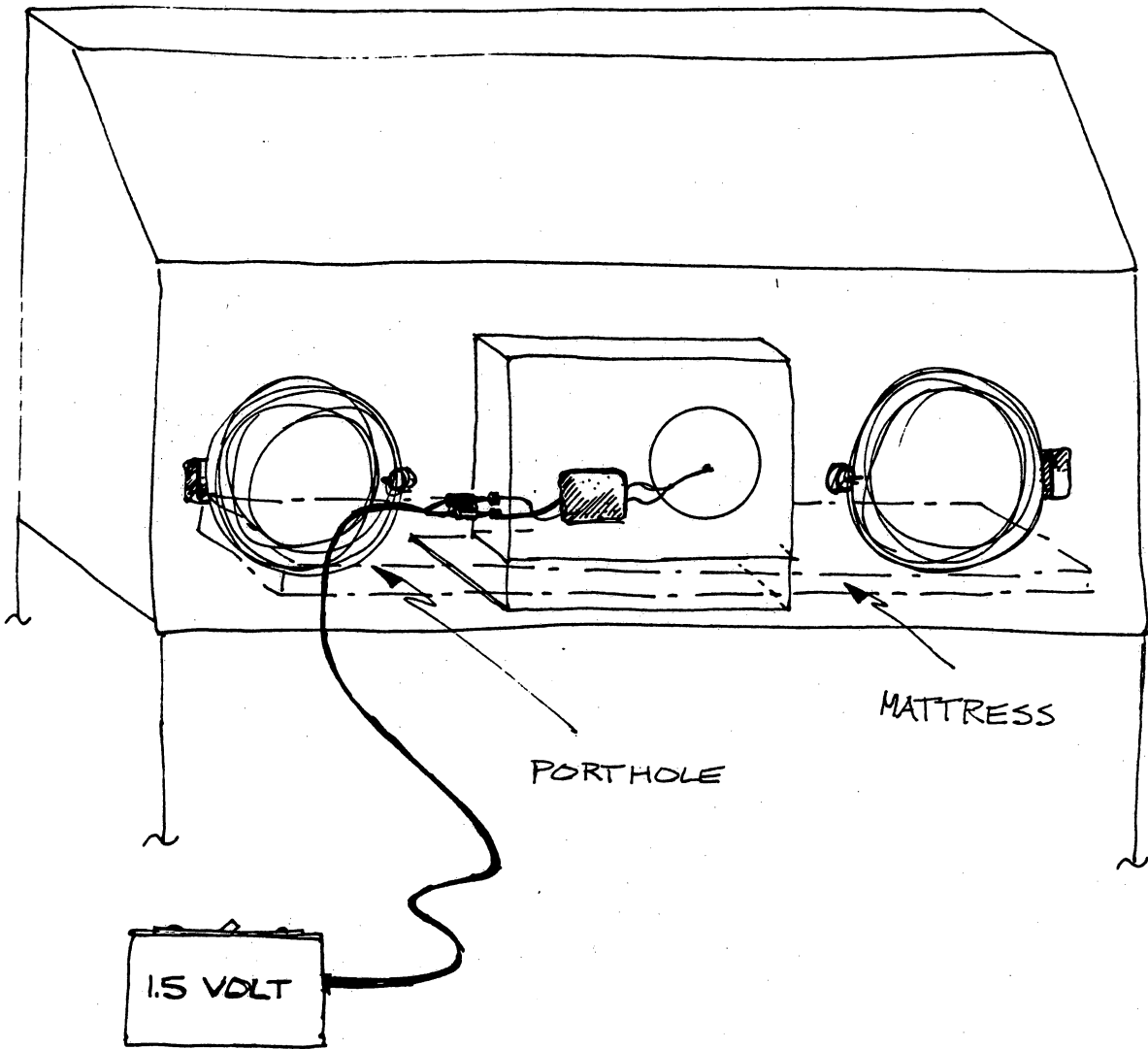
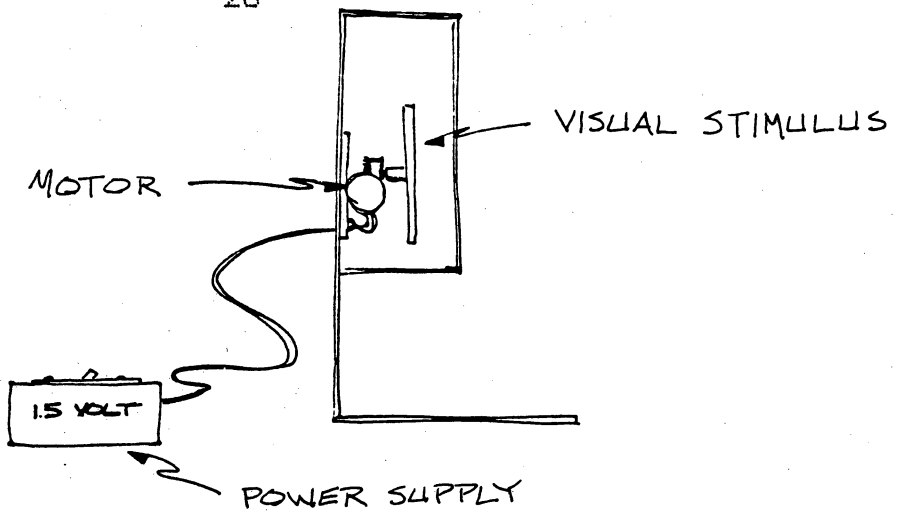


Figure 3. Visual Stimulus; Power Supply

### Procedure

When the infant was observed to be in either a drowsy, transitional or in an alert, inactive state (see Table 2), the observation period began. A sheet of neutral density film was placed over the incubator to lower illumination levels. Lower levels of illumination facilitate state maturity in preterm infants (Glass & Sostek, 1984). Though beneficial effects of the film, similar to grey acetate, would not be observed in this study, the lower level of illumination may have encouraged each infant to better attend the visual stimuli.

Physiological and motor responses have been used as indicators of psychological processing for subjects who are not able to communicate verbally (Campos, 1976). Heart and respiratory rates are functions of the autonomic nervous system and are affected by environmental stimuli (Lewis, 1974; Porges, 1974). The experimenter and an assistant recorded heart and respiratory rates as determined by the ECG/Respiration monitors to which the infants were attached. The monitor registered an averaged heart and respiratory rate on either a digital or dial display.

Recent research has focused on the development of competence in newborn and young infants. The Brazelton Neonatal Behavioral Assessment Scale (BNBAS) was developed to measure competence and adaptation in young infants (Brazelton, 1973). This scale, BNBAS, was later modified to assess the compe-

tence and behavioral assessment of prematurely born infants. The modified BNBAS, known as the Assessment of Preterm Infants' Behavior (APIB) consists of six packages of increasingly demanding environmental inputs (Als, Lester, Tronick, & Brazelton, 1981). Each package places a demand on a specific subsystem: the physiological system, motor system, state system, attention-interactive system, and the regularity system. In this study, state of arousal was evaluated using the APIB state scale. Behaviors encompassing six states, deep sleep, light sleep, drowsiness, quiet alert, active alert, and crying are described. Within each behavioral state are at least two sub-states. "A" states are described as "noisy, unclean, and diffuse" (p. 74), and "B" states are considered more clean and well defined. In State 4, alert state, there are three sub-states that distinguish between alert but unattending, "hyperalert" (p. 75), and sensory processing. Table 2 provides a description of each state.

The direction of the infant's gaze, focal point, was evaluated using 30° intervals. A measure of 15° indicated that the infant was looking in the direction of the visual stimulus. A measure of 90° or more indicated that the infant had shifted the entire visual field away from the stimulus (see Figure 4).

A final measure was the total amount of time the infant attended the visual stimulus. The experimenter used a stopwatch to accumulate an accurate record of time the infant

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 Table 2. Description of Behavioral States
 

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## Sleep:

- 1A: deep sleep: momentary regular breathing; eyes closed without movement; relaxed expression, no spontaneous activity; isolated startles, tremors
- 1B: deep sleep: predominantly regular breathing; eyes closed without movement; relaxed expression; no spontaneous activity; isolated startles
- 2A: light sleep: rapid eye movements under closed eyelids; diffuse disorganized movements, irregular respiration; many mouthing movements, whimpers, grimaces
- 2B: light sleep: rapid eye movements under closed eyelids; dampened startles; lower amplitude movements; irregular respiration; mild mouthing movements; isolated whimpers, sighs, smiles

## Transitional:

- 3A: drowsy: eyes opened, closed, or fluttering; open eyes with glassy look; variable activity level; diffuse movement; fussing and/or vocalization, whimpers, grimacing
- 3B: drowsy: similar to 3A but with less vocalization, whimpers, grimacing

## Awake:

- 4AL: alert: awake and quiet; minimal activity; eyes open but glazed
- 4AH: alert: awake and quiet; minimal activity; appears to be unable to break from stimulus
- 4B: bright shiny look; able to actively process and modulate sensory information; minimum motor activity

## Active:

- 5A: active: eyes opened or closed; diffuse fussing, grimacing; signs of discomfort

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Table 2. Description of Behavioral States (continued)

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5B: active: eyes opened or closed; well-defined muscle activity; fussing but not crying

Crying:

6A: crying is intense, but cry sound is strained, weak, or absent

6B: crying: rhythmic, robust crying

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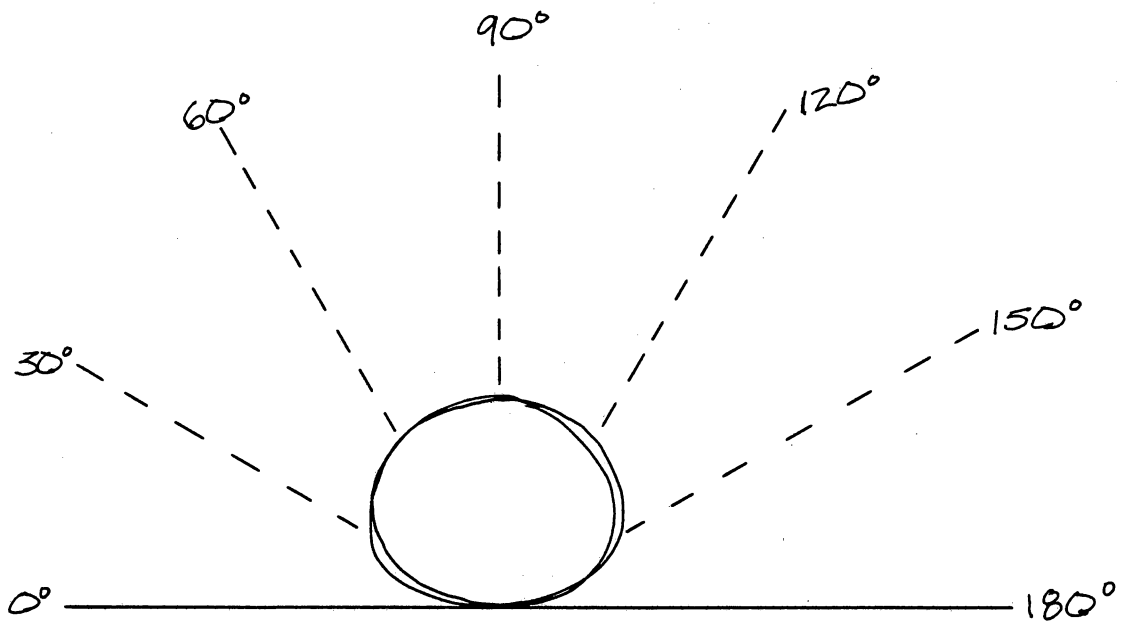


Figure 4. Focal Point Intervals

attended the visual stimulus in the stationary or nonstationary mode.

Each infant was observed on two separate days: an intervention and a nonintervention day. The intervention day consisted of a 6-minute observation period: 2-minutes baseline data, 2-minutes stimulus, 2-minutes stimulus. On the nonintervention day, the procedure was the same: the observation period began when the infant was observed to be in a drowsy, transitional, state or in an inactive, alert state. The neutral density film was placed over the incubator, and the door to the incubator opened and closed. Heart and respiratory rates, state and focal point measures were recorded for 2-minutes (Time 1). The door to the incubator was again opened and closed, and the previously mentioned measures recorded for an additional 2-minutes (Time 2). This procedure was repeated a third time (Time 3), completing a 6-minute observation period of baseline data. These three time periods for the nonintervention day, Time 1, Time 2, and Time 3, correspond to three time periods on the intervention day (see Table 3). In this procedure, each infant became his own control. Ten of the subjects were observed in an intervention/nonintervention day sequence, and ten in a nonintervention/intervention day sequence. To control maturational effects, the length of time between observation days ranged from 1 to 4 days and averaged  $1.5 \pm .89$  days.

To control the effect of opening and closing the door

Table 3. Procedure Outline

Observation Period	Heart Rate	Resp Rate	State	Focal Point	Total Time
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## INTERVENTION:

open & close incubator Baseline: 2-minutes	X	X	X	X	
-----------------------------------------------	---	---	---	---	--

open & introduce device Stationary (or nonsta- tionary stimulus): 2-minutes	X	X	X	X	X
--------------------------------------------------------------------------------------	---	---	---	---	---

open & close incubator Nonstationary (or sta- tionary stimulus): 2-minutes	X	X	X	X	X
-------------------------------------------------------------------------------------	---	---	---	---	---

## NONINTERVENTION:

open & close incubator Time 1: 2-minutes	X	X	X	X	
---------------------------------------------	---	---	---	---	--

open & close incubator Time 2: 2-minutes	X	X	X	X	
---------------------------------------------	---	---	---	---	--

open & close incubator Time 3: 2-minutes	X	X	X	X	
---------------------------------------------	---	---	---	---	--

when the device was introduced into the incubator during Time 2 on the intervention day, the incubator door was opened and closed at the beginning of each observation period. Before Time 1 data were recorded, the experimenter opened the door to the incubator, then closed it. Heart and respiratory rates, state of arousal and focal point were recorded every 10 seconds for 2-minutes to provide baseline data for the infant. The experimenter then introduced the device into the incubator. In this second 2-minute observation period, one group of infants was exposed to the visual stimulus in the stationary mode (Order 1) while a second group of infants was exposed to the stimulus in the nonstationary mode (Order 2). The same four measures were recorded in addition to the total amount of time each infant attended the visual stimulus. For the final 2-minute observation period, Time 3, the door to the incubator was opened and closed. The same five measures were recorded for either the nonstationary (Order 1) or stationary (Order 2) mode, dependent on the stimulus mode of the previous exposure period.

#### The Human Subjects Review Board

Before being accepted by the staff of the NICU at Roanoke Memorial Hospital, this research project was approved by the Human Subjects Review Board of Virginia Polytechnic Institute & State University.

### Variables

The independent variable was the presence of the device in the incubator with the visual stimulus in either the stationary or nonstationary mode.

The dependent variables were the responses to the visual stimulus in either the stationary or nonstationary mode as measured by heart and respiratory rates, state of arousal, focal point, and total time attending.

### Reliability

A trained research assistant and a second observer who had had previous experience working in the NICU assisted in the data collection. The trained assistant recorded heart and respiratory rates as they were displayed on the monitor, and recorded the experimenter's evaluation of state, focal point, and time attending. Reliability of the experimenter and assistant was assessed by comparing observations of focal point on one in ten infants. Inter-observer reliability for focal point ranged from 83% to 90% with the mean average 86.5%. Reliability of the experimenter and the experienced observer was assessed by comparing evaluation of state on one in ten infants. Inter-observer reliability ranged from 80% to 86% with the mean average 83%.

### Analysis Procedure

The research design was a repeated measures design. Each

infant was observed repeatedly in three separate conditions. Twelve data points were recorded in each observation period (baseline, stationary, nonstationary; Time 1, Time 2, Time 3), one recording every 10-seconds for 2-minutes. These raw data for each child were reduced to a mean score and standard deviation for each observation period. These scores, mean and standard deviation, were recorded and analyzed for four dependent variables: heart rate, respiratory rate, state, and focal point. One score was obtained in each stimulus period for total time attending. Each infant had one score for the first stimulus period, and a second score for the second stimulus period. To identify variation between order (stationary or nonstationary stimulus presented first) and condition (baseline, stationary, nonstationary), two 2 X 3 (order X condition) analysis of variance (ANOVAs) were conducted for four variables: heart rate, respiratory rate, state, and focal point. One ANOVA used the mean scores. The second used the standard deviation scores. To identify variation between stimulus conditions, two 2 X 2 (order X condition) analysis of covariance (ANCOVAs) were conducted for each of the four variables with baseline covaried. This procedure controls for the baseline score without testing it against the stimulus conditions. This provides clearer identification of differences between stimulus conditions (see Figure 5).

These same parametric procedures, ANOVA and ANCOVA, were used again to identify variation between intervention

ANOVA: mean

		Condition		
		Base	Sta	Nonst
Order	1			
	2			

standard deviation

		Condition		
		Base	Sta	Nonst
Order	1			
	2			

ANCOVA: mean

		Condition	
		Sta	Nonst
Order	1		
	2		

standard deviation

		Condition	
		Sta	Nonst
Order	1		
	2		

ANOVA: mean

		Time		
		1	2	3
Day	Int			
	Nonint			

standard deviation

		Time		
		1	2	3
Day	Int			
	Nonint			

ANCOVA: mean

		Time	
		2	3
Day	Int		
	Nonint		

standard deviation

		Time	
		2	3
Day	Int		
	Nonint		

Figure 5. Parametric Analysis Design

and nonintervention days. Two 2 X 3 (day: intervention, nonintervention X time: Time 1, Time 2, Time 3) ANOVAs were conducted for the mean and standard deviation scores for four variables (heart rate, respiratory rate, state, and focal point). Two 2 X 2 (day: intervention, nonintervention X time: Time 2, Time 3) ANCOVAs with Time 1 (baseline score on both days) covaried, were used to identify variation between time periods when the stimulus was presented and the corresponding time periods on nonintervention days.

The fifth variable, total time attending, was analyzed using a Student's t-test. This procedure takes into account that sample distributions for small samples deviate from the normal distribution. Evaluating the degrees of freedom determines the appropriate t-distribution.

Because the sample size was small (N=20), the possibility existed that individual differences between subjects would mask evidence or strength of responses to the stimuli. A series of nonparametric procedures which require less restrictive assumptions was initiated. Rather than evaluating the mean and standard deviation scores per se, the mean scores were measured on nominal scales. Chi-Square distributions were used to compare observed frequencies of occurrence with theoretical frequencies. Similar to the t-distribution, the appropriate X distribution is a function of the degrees of freedom. Unlike t-distributions, X distributions are associated with small degrees of freedom.

Significant effects were evaluated using  $\alpha < .05$ .

### Results

The 2 X 3 (order: stationary or nonstationary stimulus presented first X condition: baseline, stationary, nonstationary) ANOVAs revealed no significant differences in any of the variables (heart rate, respiratory rate, state, focal point) with the exception of a significant order effect in heart rate mean ( $F(1)=5.69$ ,  $p<.02$ ). Further investigation of this effect indicates a significant difference between the baseline conditions on intervention and nonintervention days (see Table 4).

The ANCOVAs with baseline condition covaried revealed no significant differences between stimulus conditions (see Table 5).

The 2 X 3 (day: intervention, nonintervention X time: Time 1, Time 2, Time 3) ANOVAs revealed significant differences in the state and focal point variables. A significant difference was apparent between mean state on intervention and nonintervention days ( $F(1)=21.86$ ,  $p<.001$ ). Mean state data also revealed a significant interaction between day and time ( $F(2)=3.24$ ,  $p<.05$ ). A comparison of cell means revealed a significant difference between Time 2 of the intervention day and Time 3 of the nonintervention day. The data indicated a significant difference in focal point variation between intervention and nonintervention days

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 Table 4. ANOVA: Order X Condition
 

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## Heart Rate Mean

		Condition		
		Base	Sta	Nonst
Order	1	140.61	150.81	148.83
	2	157.11	151.52	153.24

## ANOVA

		DF	F value	p>F
Order		1	5.69	0.02
Condition		2	0.73	0.49
Order X Condition		2	1.24	0.30

---



---

## Heart Rate Standard Deviation

		Condition		
		Base	Sta	Nonst
Order	1	6.30	7.86	5.78
	2	7.66	7.48	8.29

## ANOVA

		DF	F value	p>F
Order		1	1.79	0.19
Condition		2	0.26	0.78
Order X Condition		2	0.93	0.40

---

---

 Table 4. ANOVA: Order X Condition (continued)
 

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## Respiratory Rate Mean

		Condition		
		Base	Sta	Nonst
Order	1	35.96	32.69	36.68
	2	35.43	35.67	34.48

## ANOVA

		DF	F value	p>F
	Order	1	0.00	0.95
	Condition	2	0.61	0.55
	Order X Condition	2	1.48	0.24

---



---

## Respiratory Rate Standard Deviation

		Condition		
		Base	Sta	Nonst
Order	1	5.76	9.03	10.57
	2	6.34	5.93	6.37

## ANOVA

		DF	F value	p>F
	Order	1	2.72	0.11
	Condition	2	1.07	0.36
	Order X Condition	2	1.13	0.33

---

---

 Table 4. ANOVA: Order X Condition (continued)
 

---

## State Mean

		Condition		
		Base	Sta	Nonst
Order	1	3.52	3.63	3.74
	2	3.63	3.91	3.71

## ANOVA

		DF	F value	p>F
	Order	1	1.20	0.28
	Condition	2	1.29	0.29
Order X Condition		2	0.74	0.49

---



---

## State Standard Deviation

		Condition		
		Base	Sta	Nonst
Order	1	0.39	0.33	0.14
	2	0.44	0.13	0.10

## ANOVA

		DF	F value	p>F
	Order	1	0.23	0.64
	Condition	2	1.70	0.20
Order X Condition		2	0.28	0.76

---

---

 Table 4. ANOVA: Order X Condition (continued)
 

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## Focal Point Mean

		Condition		
		Base	Sta	Nonst
Order	1	21.43	19.75	17.78
	2	19.46	19.25	18.43

## ANOVA

		DF	F value	p>F
Order		1	0.18	0.68
Condition		2	0.83	0.45
Order X Condition		2	0.27	0.76

---



---

## Focal Point Standard Deviation

		Condition		
		Base	Sta	Nonst
Order	1	8.81	6.62	3.62
	2	8.57	10.64	8.21

## ANOVA

		DF	F value	p>F
Order		1	1.98	0.17
Condition		2	0.78	0.47
Order X Condition		2	0.61	0.30

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 Table 5. ANCOVA: Order X Condition
 

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## Heart Rate Mean

		Condition	
		Sta	Nonst
Order	1	150.81	148.83
	2	151.52	153.24

## ANCOVA

		DF	F value	p>F
	Order	1	0.75	0.40
	Condition	1	.004	0.95
	Order X Condition	1	0.79	0.39

---

## Heart Rate Standard Deviation

		Condition	
		Sta	Nonst
Order	1	7.86	5.78
	2	7.48	8.29

## ANCOVA

		DF	F value	p>F
	Order	1	0.14	0.71
	Condition	1	0.41	0.53
	Order X Condition	1	2.15	0.16

---

---

 Table 5. ANCOVA: Order X Condition (continued)
 

---

## Respiratory Rate Mean

		Condition	
		Sta	Nonst
Order	1	32.69	36.68
	2	35.67	34.48

## ANCOVA

		DF	F value	p>F
Order		1	0.17	0.69
Condition		1	0.69	0.42
Order X Condition		1	2.33	0.14

---



---

## Respiratory Rate Standard Deviation

		Condition	
		Sta	Nonst
Order	1	9.03	10.57
	2	5.93	6.37

## ANCOVA

		DF	F value	p>F
Order		1	0.83	0.37
Condition		1	3.40	0.08
Order X Condition		1	1.04	0.32

---

---

 Table 5. ANCOVA: Order X Condition (continued)
 

---

## State Mean

		Condition	
		Sta	Nonst
Order	1	3.63	3.74
	2	3.91	3.71

## ANCOVA

		DF	F value	p>F
Order		1	0.19	0.67
Condition		1	0.23	0.64
Order X Condition		1	2.63	0.12

---



---

## State Standard Deviation

		Condition	
		Sta	Nonst
Order	1	0.33	0.14
	2	0.13	0.10

## ANCOVA

		DF	F value	p>F
Order		1	1.50	0.24
Condition		1	1.40	0.25
Order X Condition		1	0.71	0.41

---

---

 Table 5. ANCOVA: Order X Condition (continued)
 

---

## Focal Point Mean

		Condition	
		Sta	Nonst
Order	1	19.75	17.78
	2	19.25	18.43

## ANCOVA

		DF	F value	p>F
	Order	1	0.43	0.52
	Condition	1	3.63	0.07
	Order X Condition	1	1.80	0.20

---



---

## Focal Point Standard Deviation

		Condition	
		Sta	Nonst
Order	1	6.62	3.62
	2	10.64	8.21

## ANCOVA

		DF	F value	p>F
	Order	1	0.72	0.41
	Condition	1	1.44	0.25
	Order X Condition	1	0.10	0.75

---

( $F(1)=8.12$ ,  $p<.01$ ) (see Table 6).

The 2 X 2 (day X time) ANCOVAs with Time 1 covaried revealed a significant mean heart rate difference between intervention and nonintervention days ( $F(1)=.72$ ,  $p<.04$ ) (see Table 7). Mean state data indicated a significant difference in time ( $F(1)=7.07$ ,  $p<.02$ ). Further investigation revealed a greater difference between Time 2 and Time 3 on the nonintervention day (see Table 7).

Analysis of the time variable indicated the existence of a strong order effect. The average amount of time attending the stimulus during the first exposure period was  $55.5 \pm 33.3$  seconds. The average amount of time attending the stimulus during the second exposure period was  $76.6 \pm 39.4$  seconds. Regardless of the stimulus mode, the second exposure period elicited a significantly lengthier time response ( $t(19)=2.01$ ,  $p<.03$ ). When the data are categorized according to longer length of time attending the stimuli, 5 of the 20 subjects looked longer at the stimulus during the first exposure period, while 15 looked significantly longer at the stimulus during the second exposure period ( $\chi^2(1)=5.05$ ,  $p<.02$ ) (see Table 8). A significant order effect is overriding response differences between stimulus modes. Consequently, the analyses will concentrate on evaluating the order effect by exploring differences between intervention and nonintervention days.

The mean heart rate data were categorized according to

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 Table 6. ANOVA: Day X Time
 

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## Heart Rate Mean

		Time 1	2	3
Day	Int	153.36	151.67	151.54
	Nonint	148.33	149.42	146.62

## ANOVA

		DF	F value	p>F
Day	Day	1	0.77	0.39
	Time	2	1.17	0.32
	Day X Time	2	0.76	0.48

---



---

## Heart Rate Standard Deviation

		Time 1	2	3
Day	Int	6.98	7.67	7.04
	Nonint	7.41	7.95	6.93

## ANOVA

		DF	F value	p>F
Day	Day	1	0.03	0.86
	Time	2	0.69	0.51
	Day X Time	2	0.04	0.96

---

---

 Table 6. ANOVA: Day X Time (continued)
 

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## Respiratory Rate Mean

		Time		
		1	2	3
Day	Int	35.70	34.18	35.58
	Nonint	37.09	36.93	38.40

## ANOVA

		DF	F value	p>F
Day	Day	1	1.48	0.24
	Time	2	1.06	0.36
	Day X Time	2	0.31	0.74

---



---

## Respiratory Rate Standard Deviation

		Time		
		1	2	3
Day	Int	6.05	7.48	8.47
	Nonint	5.37	5.77	6.77

## ANOVA

		DF	F value	p>F
Day	Day	1	0.93	0.35
	Time	2	2.09	0.14
	Day X Time	2	0.24	0.79

---

---

 Table 6. ANOVA: Day X Time (continued)
 

---

## State Mean

		Time 1	2	3
Day	Int	3.58	3.78	3.73
	Nonint	3.19	3.19	2.99

## ANOVA

		DF	F value	p>F
Day		1	21.86	.001
	Time	2	1.39	0.26
	Day X Time	2	3.24	0.05

---



---

## State Standard Deviation

		Time 1	2	3
Day	Int	0.42	0.23	0.12
	Nonint	0.10	0.74	0.26

## ANOVA

		DF	F value	p>F
Day		1	3.00	0.10
	Time	2	1.47	0.24
	Day X Time	2	1.27	0.29

---

---

 Table 6. ANOVA: Day X Time (continued)
 

---

## Focal Point Mean

		Time 1	2	3
Day	Int	20.45	19.50	18.11
	Nonint	29.18	33.88	34.93

## ANOVA

		DF	F value	p>F
Day	Day	1	3.46	0.08
	Time	2	0.25	0.78
	Day X Time	2	1.07	0.36

---



---

## Focal Point Standard Deviation

		Time 1	2	3
Day	Int	8.69	8.63	5.92
	Nonint	15.58	13.40	12.46

## ANOVA

		DF	F value	p>F
Day	Day	1	8.12	0.01
	Time	2	0.24	0.79
	Day X Time	2	0.05	0.95

---

---

 Table 7. ANCOVA: Day X Time
 

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## Heart Rate Mean

		Time	
		2	3
Day	Int	151.67	151.54
	Nonint	149.42	146.62

## ANCOVA

	DF	F value	p>F
Day	1	0.72	0.04
Time	1	0.10	0.75
Day X Time	1	0.39	0.54

---



---

## Heart Rate Standard Deviation

		Time	
		2	3
Day	Int	7.67	7.04
	Nonint	7.95	6.93

## ANCOVA

	DF	F value	p>F
Day	1	2.16	0.16
Time	1	0.00	1.00
Day X Time	1	0.84	0.37

---

---

 Table 7. ANCOVA: Day X Time (continued)
 

---

## Respiratory Rate Mean

		Time	
		2	3
Day	Int	34.18	35.58
	Nonint	36.93	38.40

## ANCOVA

	DF	F value	p>F
Day	1	0.27	0.61
Time	1	1.32	0.27
Day X Time	1	0.76	0.40

---



---

## Respiratory Rate Standard Deviation

		Time	
		2	3
Day	Int	7.48	8.47
	Nonint	5.77	6.77

## ANCOVA

	DF	F value	p>F
Day	1	0.95	0.34
Time	1	0.34	0.57
Day X Time	1	0.34	0.57

---

---

 Table 7. ANCOVA: Day X Time (continued)
 

---

## State Mean

		Time	
		2	3
Day	Int	3.78	3.73
	Nonint	3.19	2.99

## ANCOVA

	DF	F value	p>F
Day	1	0.59	0.45
Time	1	7.07	0.02
Day X Time	1	0.22	0.65

---



---

## State Standard Deviation

		Time	
		2	3
Day	Int	0.23	0.12
	Nonint	0.74	0.26

## ANCOVA

	DF	F value	p>F
Day	1	.001	0.97
Time	1	3.50	0.08
Day X Time	1	0.63	0.44

---

---

 Table 7. ANCOVA: Day X Time (continued)
 

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## Focal Point Mean

		Time	
		2	3
Day	Int	19.50	18.11
	Nonint	33.88	34.93

## ANCOVA

	DF	F value	p>F
Day	1	0.24	0.63
Time	1	1.00	0.34
Day X Time	1	0.89	0.36

---



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## Focal Point Standard Deviation

		Time	
		2	3
Day	Int	8.63	5.92
	Nonint	13.40	12.46

## ANCOVA

	DF	F value	p>F
Day	1	0.41	0.53
Time	1	3.94	0.07
Day X Time	1	0.05	0.83

---

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**Table 8. Time Variable Analysis**

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First Stimulus Period	Second Stimulus Period
-----------------------------	------------------------------

5	15
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 $\chi^2(1) = 5.05, p < .02$ 

First stimulus period:  $\bar{X} = 55.5$   
SD = 33.3

Second stimulus period:  $\bar{X} = 76.6$   
SD = 39.4

$t(19) = 2.01, p < .03$

---

an increase, decrease, or constant value from Time 1 data. Using  $\pm 4$  beats per minute (bpm) (Zeskind, in press), the data were evaluated and Chi-Square analyses conducted. On intervention days, in Time 3, a significant difference ( $X^2(2)=6.7, p<.03$ ) for the mean heart rate was evident as 5 subjects increased their heart rates, 12 decreased, and 3 remained constant. On nonintervention days, Time 3, the mean heart rate increased for 3 subjects, decreased for 5, and remained constant for 12 ( $X^2(2)=6.7, p<.03$ ) (see Table 9).

The mean respiratory rates for intervention and nonintervention days were also categorized according to an increase or decrease in Time 2 and Time 3 data from Time 1 data. A ranking of  $\pm 4$  breaths per minute was determined by dividing each infant's heart rate per minute by respiratory rate per minute. The group mean score equaled 4 breaths per minute. No significant differences were found between Time 3 intervention and nonintervention day mean respiratory rates ( $X^2(2)=4.3, p<.11; X^2(2)=2.5, p<.19$ ), or between Time 2 intervention and nonintervention day mean respiratory rates ( $X^2(2)=5.2, p<.07; X^2(2)=2.8, p<.25$ ) (see Table 10).

The state data were reduced from a possible 13 point scale to a 6 point scale. The sub-states (A and B) as described in APIB were eliminated, reducing the scale to the more general 6 point scale proposed by Wolff (1966). APIB states 1A and 1B (deep sleep) correspond to Wolff's State 1 (regular sleep). Similarly, states 2A and 2B (light sleep)

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 Table 9. Heart Rate Variable Analysis
 

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		Time 2			
		Increase	Decrease	Constant	
Int		9	8	3	$\chi^2 (2)=3.1, p<.21$
Nonint		4	3	13	$\chi^2 (2)=9.1, p<.01$

		Time 3			
		Increase	Decrease	Constant	
Int		5	12	3	$\chi^2 (2)=6.7, p<.03$
Nonint		3	5	12	$\chi^2 (2)=6.7, p<.03$

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**Table 10. Respiratory Variable Analysis**

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		Time 2			
		Increase	Decrease	Constant	
Int		2	8	10	$\chi^2 (2) = 5.2, p < .07$
Nonint		4	6	10	$\chi^2 (2) = 2.8, p < .25$

		Time 3			
		Increase	Decrease	Constant	
Int		4	5	11	$\chi^2 (2) = 4.3, p < .11$
Nonint		5	5	10	$\chi^2 (2) = 2.5, p < .29$

---

correspond to State 2 (irregular sleep), states 3A and 3B (drowsy) to State 3 (drowsiness), states 4AL, 4AH, and 4B (alert) to State 4 (alert inactivity), states 5A and 5B (active) to State 5 (waking activity), and states 6A and 6B (crying) to State 6 (crying). For purposes of this study, State 4 would be the optimal response to the visual stimulus. Wolff described State 4 as "alert inactivity: The eyes are open and bright. The child can pursue moving objects and make conjugate eye movements in the horizontal and vertical plane. The infant is relatively inactive. The face is relaxed without grimace" (p. 17).

The mean state data in Time 3 were categorized according to proximity to state 4. A measure  $\geq 3.5$  was considered a more desirable state than values  $\leq 3.5$ , which approaches a drowsy or transitional state. On the intervention day in Time 3, 17 subjects were significantly closer to State 4 compared to 3 subjects who were closer to State 3 ( $\chi^2(1)=9.85$ ,  $p<.003$ ). In contrast, only 5 subjects on the nonintervention were closer to state 4 in Time 3 and 15 closer to State 3 ( $\chi^2 = 5.05$ ,  $p<.02$ ), indicating that on the nonintervention day, the subjects generally dropped in state (see Table 11). In comparison, in Time 2 on the intervention day, 13 infants were closer to State 4, and 7 infants closer to state 3 ( $\chi^2(1)=1.85$ ,  $p<.17$ ). On the nonintervention day for Time 2, 5 infants were closer to State 4 and 15 closer to State 3 ( $\chi^2(1)=5.05$ ,  $p<.02$ ) which supports the nonintervention day re-

Table 11. State Variable Analysis

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	Time 2		
	$\geq 3.5$	$\leq 3.5$	
Int	13	7	$\chi^2 (1)=1.85, p<.17$
Nonint	5	15	$\chi^2 (1)=5.05, p<.02$

	Time 3		
	$\geq 3.5$	$\leq 3.5$	
Int	17	3	$\chi^2 (1)=9.85, p<.002$
Nonint	5	15	$\chi^2 (1)=5.05, p<.02$

---

sults in Time 3.

As with the other variables, the mean focal point data were categorized according to proximity to  $15^\circ$ , the position of the infant's eyes when looking at the stimulus. A range of  $\pm 5^\circ$ , was used to evaluate whether or not the infant was attending the stimulus. Without looking directly at a  $15^\circ$  angle, the infant may have been attending the stimulus through peripheral vision. On the intervention day in Time 3, a significant number of infants, 15, fixed their gaze in the  $10^\circ - 20^\circ$  range compared to 5 whose visual field fell below  $10^\circ$  or exceeded  $20^\circ$  ( $X^2(1)=6.42$ ,  $p<.01$ ). On the nonintervention day in Time 3, the visual field of 9 infants was between  $10^\circ - 20^\circ$ . The visual field of 7 was not within the  $10^\circ - 20^\circ$  range ( $X^2(1)=.31$ ,  $p<.58$ ). The difference between the number of infants in the sample, 20, and the number of infants observed for this measure, 16, is explained by 4 infants who had eyes closed during this observation period. For Time 2 on the intervention day, the visual field of 14 infants was between  $10^\circ - 20^\circ$ , and that of 6 infants not in the  $10^\circ - 20^\circ$  range ( $X^2(1)=3.25$ ,  $p<.07$ ). For Time 2 on the nonintervention day, the gaze of 8 infants was between  $10^\circ - 20^\circ$ , and out of the range for 9 infants ( $X^2(1)=.12$ ,  $p<.73$ ) (see Table 12).

In summary, the data indicated significant differences in infant responses between intervention and nonintervention days. On the intervention days, the infants attended the visual stimulus during Time 3 a significantly longer period

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 Table 12. Focal Point Variable Analysis
 

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		Time 2		
		$10^{\circ} < x < 20^{\circ}$	$10^{\circ} > x > 20^{\circ}$	
Int		14	6	$\chi^2(1) = 3.25, p < .07$
Nonint		8	9	$\chi^2(1) = .12, p < .73$

		Time 3		
		$10^{\circ} < x < 20^{\circ}$	$10^{\circ} > x > 20^{\circ}$	
Int		15	4	$\chi^2(1) = 6.42, p < .01$
Nonint		9	7	$\chi^2(1) = .313, p < .58$

---

of time, regardless of stationary or nonstationary mode. The data revealed a significant decrease from baseline (Time 1) in heart rate mean during the second stimulus exposure period (Time 3). In contrast, on nonintervention days, the infants' heart rates remained constant a significant number of times. Respiration appeared to remain stable across stimulus conditions and between days. The infants' state of arousal rose significantly closer to a State 4, alert inactivity, during Time 3 on intervention days, while dropping significantly to a more drowsy, transitional state during the same time period on nonintervention days. In addition, the infants' focal point fell within a  $10^{\circ}$  -  $20^{\circ}$  range a significant number of times during the stimulus exposure period in Time 3.

#### IV. Discussion

The results of this study indicate that preterm infants will attend a visual stimulus placed adjacent to them inside the incubator. Statistically identifiable responses were observed when intervention and nonintervention data were analyzed. In general, the infants were orienting to the visual stimulus, regardless of mode (stationary or nonstationary) as evidenced by an increase in length of time attending the stimuli, deceleration in heart rate, rise to an alert state, and direction of gaze.

An unexpected outcome is that the infants prefer the second stimulus period (Time 3), whether the stimulus is stationary or nonstationary. This does not support the findings of McKenzie and Day (1976) who concluded that a nonstationary stimulus elicited more attention than a stationary stimulus in 9 and 16 week old full-term infants. The anticipated result with preterm infants whose sensory information processing capabilities are less mature was that the nonstationary stimulus would present too much stimulation, and the infants would avert their gaze (Als, 1985; Field, 1981). Consequently, the infants would prefer the stationary over the nonstationary stimulus.

One explanation for this finding is the process of adaptation to a change in the environment. As evidenced by the data in Time 3 on intervention days, significant

responses to the stimuli are evident for each measure with the exception of respiratory rate. In Time 2, however, on intervention days, the only measure that approaches significance is focal point. This supports the hypothesis that the infants are processing information about the stimulus. They appear to be looking in the  $10^{\circ}$  -  $20^{\circ}$  range more often than they did on the nonintervention day in Time 2 (14 on the intervention day and 8 on the nonintervention day), and, though changes in heart rate and state may not be significant, the raw numbers indicate some differences in those measures. On the intervention day, heart rates of 8 infants decrease. On the nonintervention day, 3 decrease. For state on the intervention day, 13 infants are approaching State 4 ( $\geq 3.5$ ), while 5 approach State 4 on the nonintervention day. The infants may look at the stimulus, look away, and look back, processing stimulus information without orienting. By the time of the second stimulus period, Time 3, the infants are organized and capable of attending and processing information as evidenced by orienting responses.

A second explanation proposed by Parmelee and Sigman (1976) is that a longer fixation may not be the result of more intense investigation, but evidence of an immature form of behavior, an inability to inhibit gazing. Though difficult to evaluate at this point, this fixation may be a positive exercise for the infant. More experience with different types of stimuli may facilitate the infant's ability to

discriminately process sensory information. Porges, Stamps, and Walter (1974) suggest that long latency may be cognitively oriented.

A third explanation concerns adaptation to different levels of illumination as a function of time. The neutral density film was placed over the incubator at the beginning of the observation period, immediately lowering the level of illumination. By the time of the second stimulus exposure period, Time 3, the infants' eyes may have adjusted to the lower illumination level which enabled them to better attend the visual stimulus.

A final explanation may also be found in the nature of the testing procedure. Even though the incubator is opened and closed at the beginning of each time period, there is a difference between Time 2 and Time 1 and 3. During Time 2, the device is slipped into the incubator and the hinged panel slipped underneath the mattress. Though the infants are not handled, there are confounding forms of stimulation taking place: some manipulation of mattress, more sound, and the incubator is open for a longer period of time. This influx of sensory information may upset the infant, requiring a period of time to stabilize and reorganize.

An interesting difference between the mean heart rate data on the intervention and nonintervention days in Time 3 is that on the intervention day, the heart rates of 12 infants decreased, evidence of an orienting response (Berg,

1974; Graham & Clifton, 1966; Lewis, Kagan, Campbell, & Kalafat, 1966; Pomerleau-Malcuit, Malcuit, & Clifton, 1975; Sameroff, Cashmore, & Dykes, 1973). On the nonintervention day, the heart rate of 12 infants remained constant. In contrast, in Time 2 on the intervention day, the heart rates of 9 infants increased while 8 decreased, and 3 remained constant. Though not significantly different ( $X^2(2)=3.1$ ,  $p<.21$ ), the sum of the infants who responded with an increase or decrease in heart rate, both signs of attention (Sameroff, 1971; Strouf & Waters, 1977), suggests an alternative conclusion. Seventeen infants responded in Time 2 with either an increase or decrease in heart rate while 3 remained constant ( $X^2(1)=9.85$ ,  $p<.002$ ), evidence of a significant response, not orientation, to the stimulus. In comparison, data on the nonintervention day for Time 2 reveals that a significant number of infants stayed the same (13) while 4 had increased heart rates and 3 decreased ( $X^2(2)=9.1$ ,  $p<.01$ ). Again the data suggest that the infants may be responding to the stimulus in Time 2 on intervention days without orienting.

An important finding with regard to respiratory activity is that although no significant effects were evident, the infants' respiration remained stable across observation periods, regardless of day (intervention or nonintervention) or stimulus condition (stationary or nonstationary). The infants were neither holding their breaths nor breathing rapidly during exposure to the stimulus.

In the final analysis, even though the focal point measure seemed weak in design, significant results were evident. The infants did fix their gaze on the stimulus a significant number of times in Time 3 on the intervention day. The number of infants who fixed their gaze on the stimulus in Time 2 on intervention days approached significance. One factor to consider in the analysis of this variable is the physical strength of the infant. Preterm infants do not have the strength or neuromuscular maturity to gently turn their heads to change their visual fields. Conceptionally older preterm infants typically have elongated heads, the result of weeks or months spent with their heads to one side or the other. When they develop the strength to turn their heads, balance becomes an issue. Consequently, even after this ability to turn their heads develops, they lack the strength or skill to hold their heads in an upright position. As a result, their visual field is typically oriented to one side or the other. Though focal point is a valid measure to evaluate direction of gaze, it should be modified to become a more sensitive measure. In this study, focal point was measured in 30° intervals with the exception of 15° which indicated the infant was looking in the direction of the stimulus. These degree intervals measured only one plane of vision, and did not take into account that the infant's eyes may be focusing at 15° , but looking above or below the stimulus. A more accurate measure

would be to superimpose a grid over the incubator and record points of gaze rather than angle of gaze.

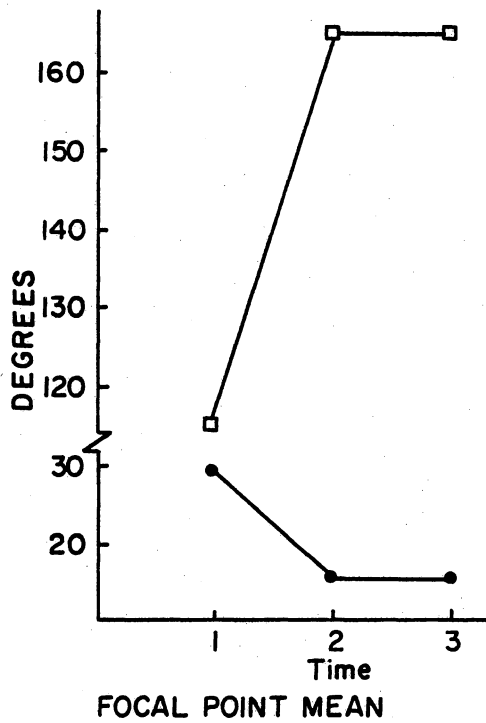
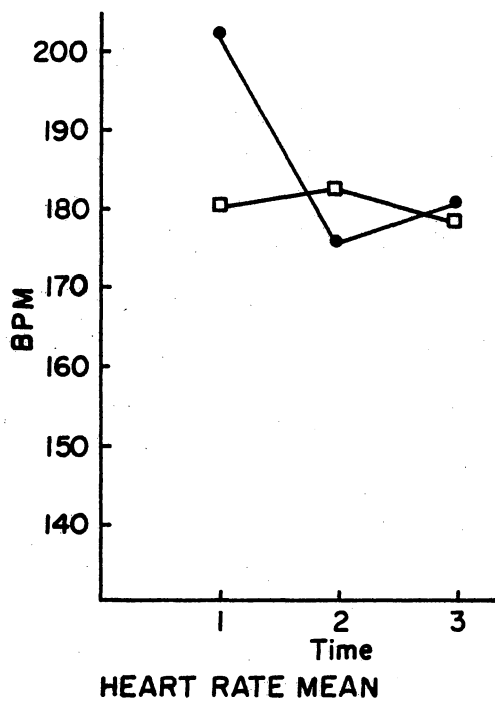
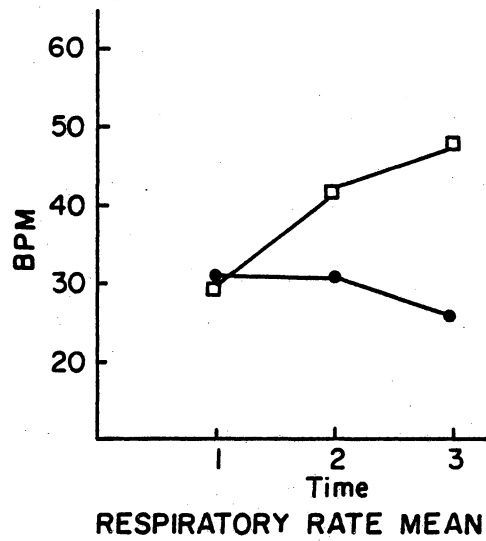
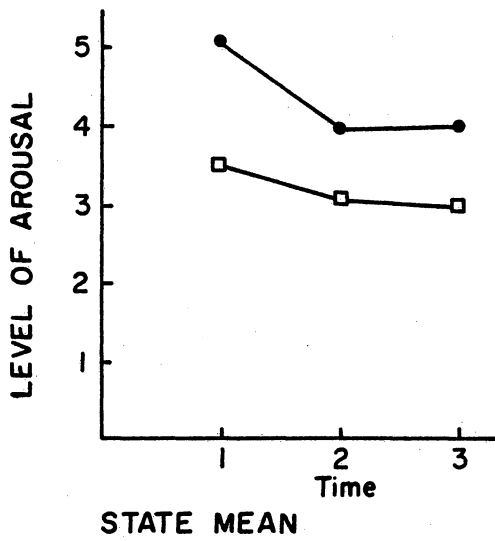
### Conclusion

This research proposed to design and evaluate a visual stimulation device that is appropriate for preterm infants. The question being asked was whether or not the infants would attend a visual stimulus placed adjacent to the infant inside the incubator. Measures recorded to address this question included heart and respiratory rates, evaluation of state, focal point, and length of time attending the device. Evidence of an orienting response included a deceleration in heart rate. Attention to the stimulus was measured by an evaluation of state: was the device making the subjects drowsy, or was it capturing their attention and bringing them to an alert state? Focal point attempted to record direction of gaze: were the infants actually looking at the device? Length of time attending the device provided an accurate record of the amount of time within each 2-minute stimulus period that the infant actually attended the device. The findings indicate that the subjects did orient to the stimulus as evidenced by deceleration in heart rate, and that they became more alert (state) while attending the visual stimuli (focal point and time).

Though generalizations have been made concerning the evaluation of the visual stimulation device, a critical

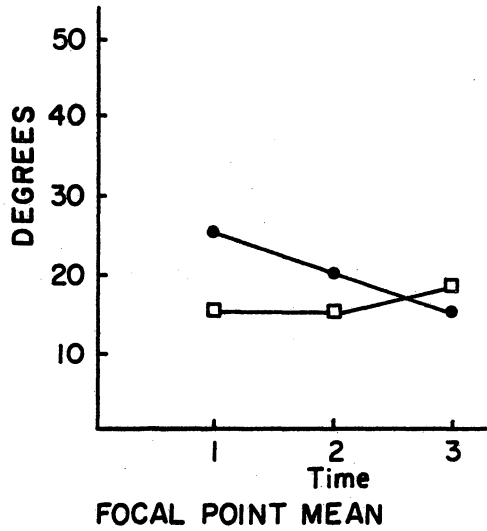
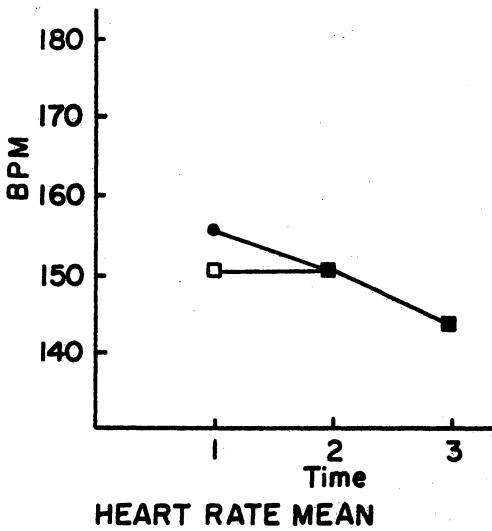
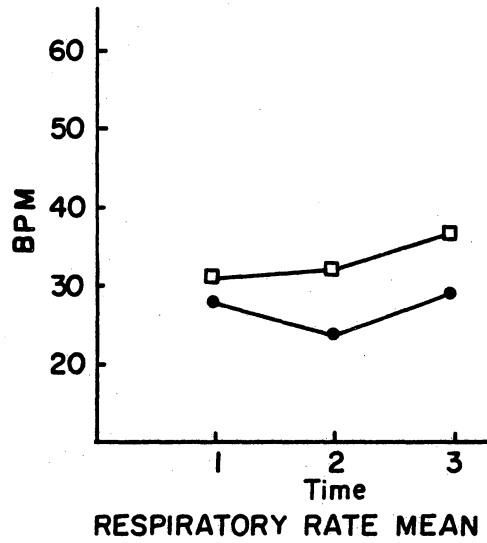
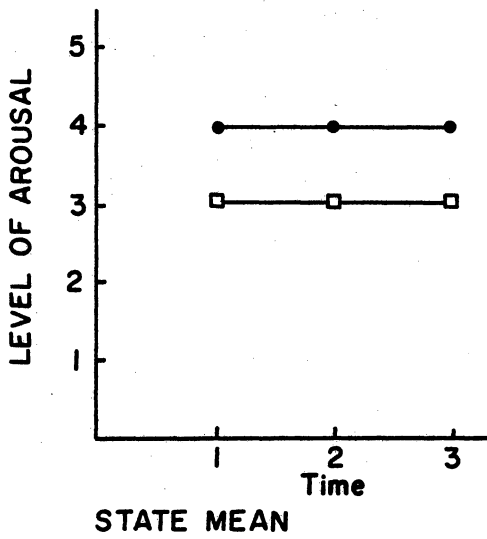
finding is the consideration of differences between individuals. In a particular case, one subject was becoming fussy when the observation period began. With the introduction of the device, her state dropped from 5 to 4, and remained there throughout the intervention period. Her heart rate dropped from an average of 202 bpm to 176 and then to 181. Her respiration rate held constant at approximately 31 breaths per minute. Her focal point varied between 15° and 30°. She spent 83 seconds attending the stationary stimulus (presented first), and 120 seconds attending the nonstationary (see Figure 6). In contrast, a different subject began the observation period in a well organized State 4. Almost immediately into the first intervention period (nonstationary presented first), he developed hiccups, a defensive gesture. By the end of the first intervention period, he was averting his gaze, at one point turned his head to 60°, and placed one hand, open-palm, against his face. At the end of the first observation period, his arms were bent at the elbows, fist hands placed near his ears, and he had begun to close his eyes. This series of defensive gestures (Als, 1985; Field, 1981; Stroufe & Waters, 1977) indicate that the stimulus was too much for him even though no severe degree of anxiety seemed apparent in the variable measures (see Figure 7).

The significance of individual differences is also apparent in the ANCOVA results. The responses of infants to



● INTERVENTION  
 □ NONINTERVENTION

Figure 6. Individual Subject Response: Orienting



● INTERVENTION  
 □ NONINTERVENTION

Figure 7. Individual Subject Response: Defensive Gestures

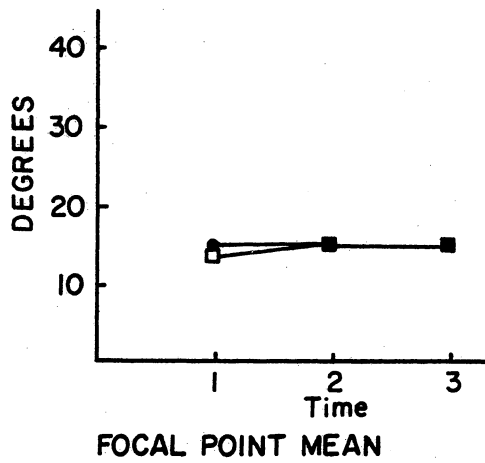
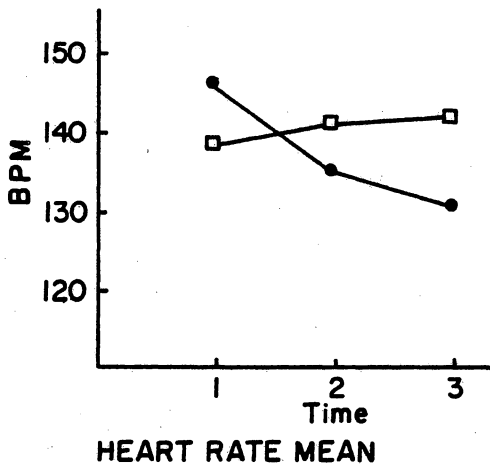
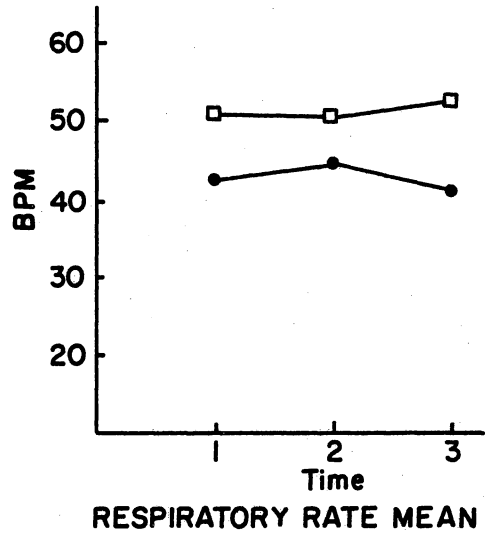
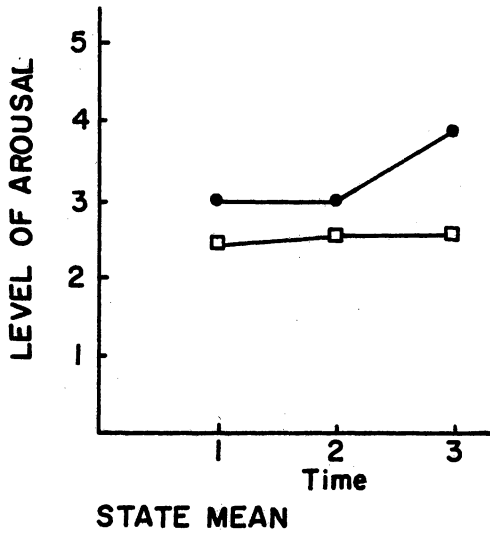
environmental stimulation may be dependent on each infant's condition during the baseline observation period. Infants with higher resting heart rates may respond with a deceleration in heart rate during exposure to a stimulus. Infants with lower heart rates may respond to environmental stimulation with accelerated heart rates. The amount of individual heart rate variability may also affect a response to environmental stimuli. Variations in individual heart rates may reflect a number of events that have occurred as a result of a prenatal or birth condition. Other environmental influences include the time of the last feeding or effects of a particular medication (Forges, 1974). In addition, the infant's state of arousal during baseline may have an effect on the response to a particular environmental stimulus (Campos & Brackbill, 1973). Infants beginning the observation period in a State 3 may become more alert to the stimulus. Infants in State 5 (fussy), already aroused at the beginning of the observation period, may respond by averting their gaze. The ANCOVA results, rather than displaying few significant effects, may be emphasizing the differences between individual subjects as each experiences variations in environmental stimulation.

In summary, though the subjects generally appeared to orient to the visual stimulus, the conclusion is that individual differences between infants may never be overlooked. A stimulus that appears appropriate for one

infant may not be appropriate for the next infant. Should the device evaluated in this study become the vehicle for a long-term visual stimulation study, continuous evaluation of each subject during exposure to the device will be necessary.

## V. Suggestions for Further Research

Though the measures indicate that preterm infants would attend a visual stimulation device placed in the incubator, the findings of this study raise a number of other issues. The most unexpected result was the preference for the second stimulus time period regardless of stimulus mode. Would a different visual stimulus have been more appropriate? Do different gestational or conceptional age infants need a simpler or more complex stimulus? Would full-term infants react differently to the stimuli than the preterm infants? Was the speed of rotation (1 cycle per 2 seconds) too fast or too slow? More importantly, was the length of the observation period (each at 2-minutes) too long? A strong orienting response could have occurred in the first 15-seconds of the observation period, but been negated by the next 1-minute 45-second length of time when the data were reduced to a mean score. In some instances, the subject was maintaining a nearly constant baseline condition on a nonintervention day while the intervention procedure produced variation within the variables (see Figure 8). Is variability good or bad? Is Parmelee and Sigman's (1976) suggestion that longer fixation reflects an inability to modulate stimulus evoked responses a valid concern? Would the end result, visual experience, enhance the maturation of the CNS or become a temporary



● INTERVENTION  
 □ NONINTERVENTION

Figure 8. Variability Between Intervention and Nonintervention Days

insult to a stabilizing system? What would the long-term effects be? Long-term exposure may or may not improve cognition, but may facilitate the quality of quiet sleep after exposure to the device. How would the response change if the visual stimulus was paired with an auditory stimulus? What would the long-term effects of this condition be?

An ideal situation to evaluate the response to this device would be to have the device in the incubator or attached to it, and record the infant's responses as he woke. This would eliminate the confounding variable of introducing the device into the incubator, and provide opportunity for measuring habituation and, eventually, dishabituation.

The findings of this study indicate that preterm infants will orient to a visual stimulus placed in the incubator. This information becomes the first step in what could become a series of investigations to determine how best to facilitate the maturation of preterm infants.

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Appendix A

Consent Form

Dear Parents:

As parents of a premature baby, you realize that your baby has special needs and requires special care. After experiencing the premature birth of my own child, I understand your feelings and concerns. Most of the care your baby will receive will be within the baby's incubator. Though essential for your baby's recovery, the incubator limits your baby's experience with everyday sights and sounds. We are examining the possibility of providing some of the sights your baby might be missing. We want to place a black and white pattern next to your baby and see if he/she will look at it. We would like you to give us permission to observe your baby.

We have designed a box that contains a striped pattern and can be placed in the incubator. We would like to show the pattern to your baby. The observation period will last about 6 minutes. During 2 of those 6 minutes, the pattern will be moving in a circular direction. We will watch the rates of your baby's heart beats and breathing as determined by the monitor your baby is already attached to. We will also observe how your baby wakes to look at the pattern, and how long your baby looks at it.

This procedure will present no harm to you or your baby, and all findings will be kept confidential. Although we will not be observing immediate benefits resulting from exposure to the black and white pattern, the findings may help babies in the future. We could really use your help. If you should have any questions, the observers would be glad to talk with you at any time.

I understand that the observers will answer any questions I have concerning the observation of my baby. I understand that I may withdraw at any time, and may prevent my baby from taking part.

I AGREE TO PARTICIPATE.

-----  
(Mother's signature)

-----  
(Date)

-----  
A. Marshall-Baker/P.S. Zeskind  
703-953-1895  
703-961-5534

-----  
(Date)

Appendix B

Data Collection Form

Data Collection Form: Visual Stimulation Project

Subject: \_\_\_\_\_ : Sex  
 Gestational Age: Birth: \_\_\_\_\_ : Test Date  
 Birthweight: \_\_\_\_\_ : Test Weight  
 Begin Time: \_\_\_\_\_ : End Time  
 Monitor: \_\_\_\_\_ : Position  
 Medication:

	HR	RR	ST	FP	TT
:10	_____	_____	_____	_____	
:20	_____	_____	_____	_____	
:30	_____	_____	_____	_____	
:40	_____	_____	_____	_____	
:50	_____	_____	_____	_____	
1:00	_____	_____	_____	_____	
:10	_____	_____	_____	_____	
:20	_____	_____	_____	_____	
:30	_____	_____	_____	_____	
:40	_____	_____	_____	_____	
:50	_____	_____	_____	_____	
2:00	_____	_____	_____	_____	
:10	_____	_____	_____	_____	
:20	_____	_____	_____	_____	
:30	_____	_____	_____	_____	
:40	_____	_____	_____	_____	
:50	_____	_____	_____	_____	
3:00	_____	_____	_____	_____	
:10	_____	_____	_____	_____	
:20	_____	_____	_____	_____	
:30	_____	_____	_____	_____	
:40	_____	_____	_____	_____	
:50	_____	_____	_____	_____	
4:00	_____	_____	_____	_____	_____
:10	_____	_____	_____	_____	
:20	_____	_____	_____	_____	
:30	_____	_____	_____	_____	
:40	_____	_____	_____	_____	
:50	_____	_____	_____	_____	
5:00	_____	_____	_____	_____	
:10	_____	_____	_____	_____	
:20	_____	_____	_____	_____	
:30	_____	_____	_____	_____	
:40	_____	_____	_____	_____	
:50	_____	_____	_____	_____	
6:00	_____	_____	_____	_____	_____

Appendix C

Human Subjects Review Board

CERTIFICATION OF EXEMPTION OF PROJECTS  
INVOLVING HUMAN SUBJECTS

Principal Investigator(s) ANNA MARSHALL-BAKER

Department(s) HOUSING, INTERIOR DESIGN & RESOURCE MANAGEMENT

Project Title DEVICE TO PROVIDE VISUAL STIMULATION TO INFANTS CONFINED

Source of Support: Departmental Research  Sponsored Research  Proposal No. IN INVESTIGATORS

1. The criteria for "exemption" from review by the IRB for a project involving the use of human subjects and with no risk to the subject is listed below. Please initial all applicable conditions and provide the substantiating statement of protocol.

- a. The research will be conducted in established or commonly established educational settings, involving normal education practices. For example:
  - a) Research on regular and special education instructional strategies;
  - b) Research on effectiveness of instructional techniques, curricula or classroom management techniques.
- b. The research involves use of education tests ( cognitive,  diagnostic,  aptitude,  achievement), and the subject cannot be identified directly or through identifiers with the information.
- c. The research involves survey or interview procedures, in which:
  - a) Subjects cannot be identified directly or through identifiers with the information;
  - b) Subject's responses, if known, will not place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability;
  - c) The research does not deal with sensitive aspects of subject's own behavior (illegal conduct, drug use, sexual behavior or alcohol use);
  - d) The research involves survey or interview procedures with elected or appointed public officials, or candidates for public office.
- d. The research involves the observation of public behavior, in which:
  - a) The subjects cannot be identified directly or through identifiers;
  - b) The observations recorded about an individual could not put the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability;
  - c) The research does not deal with sensitive aspects of the subject's behavior (illegal conduct, drug use, sexual behavior or use of alcohol).
- e. The research involves collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, or which:
  - a) The sources are publicly available; or
  - b) The information is recorded such that the subject cannot be identified directly or indirectly through identifiers.

*THIS PROJECT IS EXEMPT BECAUSE THE SUBJECTS DO NOT MEET THE DEFINITION OF HUMAN SUBJECTS PER 45 CFR 101.12*

2. I further certify that the project will not be changed to increase the risk or exceed the exempt condition(s) without filing an additional certification or application for approval by the Human Subjects Review Board.

Note: If children are in any way at risk while this project is underway, the chairman of the IRB should be notified immediately in order to take corrective action.

Signature: Principal Investigator(s) 26 April 85 Date Signature: Principal Investigator(s) \_\_\_\_\_ Date

(Optional Approval) Signature: Board Chairman/Authorized Reviewer 4/15/85 Date

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