Development of a system for respiratory augmentation

Leon Joseph Arp
Iowa State University

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Iowa State University of Science and Technology,
Ph.D., 1966
Education, general

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U.S. PATENTS APPLIED FOR
on all apparatus developed for
and described in this dissertation
DEVELOPMENT OF A SYSTEM FOR RESPIRATORY AUGMENTATION

by

Leon Joseph Arp

A Dissertation Submitted to the Graduate Faculty in Partial Fulfillment of The Requirements for the Degree of DOCTOR OF PHILOSOPHY

Major Subject: Education

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Dean of Graduate College

Iowa State University
Of Science and Technology
Ames, Iowa

1966
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INTRODUCTION

Respiratory distress syndrome (R.D.S.), also called hyaline membrane disease, and recently described as "The Pulmonary Hypoperfusion Syndrome" (1) is responsible for the deaths of more newborn infants (neonates) than any other disease. The death rate for children has fallen dramatically over the past 20 years with the exception of those children under one week of age. An estimated 25,000 neonates expire each year in the United States (2). This number represents between 30 and 40 per cent of all neonatal deaths (3). R.D.S. is characterized by pulmonary insufficiency which occurs in the first few days after birth. It occurs most often in premature infants, infants of diabetic mothers, those born by cesarean section, and infants born of mothers who experienced intrauterine bleeding.

Clinically, the infants are often resuscitative problems at birth and soon develop the classic symptoms of R.D.S., labored breathing with a dramatic increase in rate from the normal 40 breaths per minute to as high as 125 breaths per minute. Inspiratory retractions of the sternum and rib cage and expiratory grunting are additional clinical manifestations of the severely distressed infant. Physical examination reveals harsh breath sounds, often with fine rales on deep inspiration. The general impression is that there is very poor air exchange. Progressive cyanosis and periods of apnea usually indicate impending death. The cause of respiratory distress is unknown.

It is known that the compliance of the lung is drastically reduced by the hyaline-like membrane which sometimes covers the alveoli. This membrane causes atelectasis of many of the alveoli, thus reducing, and in some instances, preventing normal gaseous exchange with the blood.

The decrease in the number of alveoli actively involved
in gaseous exchange with the blood, as well as the decrease of active surface area of the partially functioning alveoli, causes an increase in the carbon dioxide content of the blood and a decrease in pH. The reduced compliance and associated atelectasis may increase the amount of pulmonary work required to maintain a normal gas flow in and out of the lungs by as much as 400 per cent (4).

Autopsy findings include: Collapsed firm, liver-like, dark red lungs with microscopic sections showing protein deposits in the alveoli, alveolar collapse, thick walls in arterioles, and small lumen. Biochemical studies show a decrease or near absence of surfactant.

A good discussion of the general requirements for a respirator and the justifications for assisting or augmenting the inspiratory efforts of the newborn in respiratory distress is found in a doctoral thesis, *Engineering Aspects of Neonatal Respiratory Augmentation* by Dr. David L. Carlson. This study is an unpublished dissertation in the Iowa State University library, Ames, Iowa (3).

Clinical use of the Carlson and Arp-Varnum respirators showed a need for certain other pieces of equipment, not commercially available, to successfully treat the neonatal patient suffering from respiratory distress. It was very difficult to connect a respirator to a patient in an incubator since access to the patient was severely restricted by the incubator. In addition, the attending physicians and nurses must have easy access to the infant for examinations, suctioning, placing of catheters for blood gas samples, etc. Therefore, it was desirable to treat the infant out of the incubator. It is a well-known fact that the infant's temperature must be kept at a normal level. Oxygen consumption, by the infant, increases at a rapid rate as body temperature deviates from the normal range. Some suitable method of maintaining the infant's temperature at a normal level was needed.
This, of course, required the temperature to be continuously measured, and displayed while automatically controlling any additional heat which might be required to keep the infant's temperature at a normal level. It was also decided that the temperature measuring device should, while monitoring and displaying the temperature, also contain alarms and signals to warn if the patient's temperature deviated either above or below a selected normal value and to signal continuously while the heater was in operation.

Nearly unobstructed access to the patient by the physicians and nurses was obtained by designing a special bed-like holding device to support the infant. The bed was designed so as not to interfere with the serial chest radiographs used for diagnosis and for determining the daily progress of the patient.

Early in the clinical development of the respiratory support system it became obvious that the chest radiographs were not of uniform quality and density. Changes in the condition of the patients could not fully account for the observed changes in the films. It was determined that the degree of inflation of the patient's lungs was not uniform from one radiograph to another and caused a change in the appearance of the film, which made it difficult to determine the degree of actual change in condition of the patient which had taken place. At this time, a special triggering circuit was added to the respirator to trip the X-ray machine at the end of a selected delivery stroke of the respirator, thereby guaranteeing consistent inflation of the lungs from one radiograph to another.

The Carlson and The Arp-Varnum respirators used in the clinical evaluation of the augmentation system are volume limited machines; therefore, knowledge of the spontaneous expiratory tidal volume of the patient was desired. Existing spirometers were not suitable for measuring the small volumes
(5 to 25 cm.\(^3\)) and required pressures far in excess of the 2 to 3 mm. H\(_2\)O pressure deemed acceptable for the infant to exhale against.

A single breath spirometer requiring 2 to 3 mm. H\(_2\)O pressure for operation was designed, and has been used, to determine the infant's spontaneous expiratory tidal volume. The tidal volume information has been used to make a decision as to the volume selected to be delivered by the respirators.

This study outlines the major considerations necessary in the design, construction, and clinical evaluation of the following items making up the system for respiratory augmentation: A spirometer for determining the patient's tidal volume, a volume limited respirator, a bed for holding and supporting the infant during treatment, an addition to the respirator for automatically triggering an X-ray machine immediately after a tidal volume has been delivered to the patient, and a temperature sensor, indicator-controller mechanism to monitor and display the infant's temperature and to control a heater for maintaining the infant's temperature in a normal range.

A discussion of the experimental and clinical results achieved from the use of the various pieces of equipment is also included in this study.
SINGLE BREATH SPIROMETER

Introduction

Physiologists have been searching for a means of measuring the tidal volume of the lungs (volume of air inhaled or exhaled while at rest) on a breath-by-breath basis.

Spirometers used up to this time have been of three general types: the whole body plethysmograph, the bag-in-box recording spirometer, and the submerged vessel or bell type recording spirometer. Each of these spirometers has some undesirable trait which renders it unsatisfactory for general clinical use with neonates.

The whole body plethysmograph is not readily available in any hospital other than research institutions. It requires expensive and delicate electronic apparatus to function properly and generally cannot be successfully used by most physicians and nurses unless they are specifically trained for the use of research methods and equipment (5). Nelson et al., in discussing the whole body plethysmograph, say "...blood collections are very difficult since the infant is enclosed in the plethysmograph. Gas collections are awkward and require closed circuitry with large volumes of diluting gas forced past the infant's nares to prevent build up of CO₂ (5)." The bag-in-box recording spirometer and the submerged vessel or bell type spirometer requires greater pressures for operation than can be tolerated or supplied by the infant. These systems are not practical for clinical use and do not give the volume of each breath, but rather, an average volume of several breaths.

Several requirements for a clinically useful single breath spirometer may be set forth. Resistance to the infant's respiratory efforts must be small. Total allowable pressure required to operate the spirometer must not exceed 2 or 3 mm. H₂O. The machine should be clinically useful.
That is, it must be able to be easily used by non-engineering-type personnel such as nurses and doctors. Finally, the spirometer must be accurate and give reproducible results. Errors must not exceed \( \pm 0.5 \text{ cm}^3 \) over its entire volumetric range.

System Description

For descriptive purposes, the spirometer can be divided into two sections; one, the collection system, and the other, the measuring and display system. Figure 1 shows the complete spirometer.

The collection system provides the sensing and input valving functions of the spirometer. Included are the flow sensing switch, flow directing valve, sample collection chamber, and the nose mask (5) with its connecting tubing. The pneumatic system of the spirometer is shown in block diagram form in Figure 2. The flow path is bifurcated, one conduit for inspiration and another for expiration. Check valves control the direction of flow in each branch. The connecting interface between the patient and the spirometer is a Buck nasal mask (6).

Figure 2 shows the pneumatic circuitry in a standby condition awaiting actuation of the start switch. In this state the patient may freely inhale through the check valve and transducer in the inhalation side of the circuit and exhale through the other check valve and rotary valve to the by-pass post and the atmosphere. Following actuation of the start switch by the operator the next time the flow transducer is tripped by the beginning of inspiration the rotary valve is turned from the by-pass position shown to its alternate position to direct the next exhalation into the collection sack. The next inhalation, through the flow transducer causes the spring loaded rotary valve to return to the by-pass position shown. At this point in the sequential operation
Figure 1. Spirometer
Figure 2. Spirometer pneumatic block diagram
of the spirometer the exhaled tidal volume is trapped in the collection sack and the patient is free to breathe freely through the machine while the measurement of the trapped gas is being made and displayed. A solenoid which pulls the platen against the 0.005 inch thick silicone rubber collection sack, after the sample is trapped by the operation of the rotary value, forces the gas sample out of the collection sack into a selected 50 cm.$^3$ syringe. The syringe is carefully selected on the basis of securing minimum friction without leakage around the plunger. In fact, the plunger is entirely surrounded by a thin film of gas. The plunger is actually supported by an air-bearing and is counterbalanced to minimize the compression of the gas being measured in the system. A transparent scale carrying graduation marks calibrated to 0.25 cm.$^3$ is attached to the plunger of the syringe for read-out of the volume. An optical lever with a magnification of 4:1 is used to project the graduations on a ground glass screen at the front of the spirometer. The optical lever greatly expands the scale length and thereby increases the readability of the numerical read-out, thus allowing direct reading of volumes to the nearest 0.25 cm.$^3$ and to 0.06 cm.$^3$ with simple interpolation.

The measured volume is displayed on the ground glass screen at the front of the spirometer for a predetermined length of time, then the exhaust valve is opened and a solenoid forces the plunger of the syringe back to the reset position emptying the syringe. The exhaust valve is then closed and finally, to complete one tidal volume measurement, the platen solenoid is de-energized returning the spring loaded platen to the position shown in the pneumatic block diagram. A new measurement may be made at this time by actuating the push to read switch. About 10 to 12 measurements may be made per minute with this spirometer.
Figure 3 shows the spirometer's electronic block diagram. An operating cycle of the electronic section starts when the read switch is actuated. Actuation of the read switch sets the read bistable to provide one input to the "and" gate. The next time the flow transducer is tripped by an inspiration the trigger supplies the required second input signal to the two input "and" gate. The resulting output signal from the "and" gate sets the valve bistable which activates the rotary valve from the position shown in the pneumatic block diagram, Figure 2, to its alternate position. The valve bistable holds the rotary valve in the alternate position while the patient exhales. The second inhalation after the actuation of the read switch causes the flow transducer to deliver a second signal to the valve bistable through the trigger and the "and" gate causing the valve bistable to be reset to its starting position. Consequently, the spring loaded rotary valve also returns to the by-pass position. Upon resetting, the valve bistable resets the read bistable, thus removing one signal from the two input "and" gate thereby preventing the passage of additional signals from the flow transducer and trigger during subsequent inhalations during the remainder of the measuring and display cycle. Simultaneously, the valve bistable also delivers a signal upon resetting to delay one. Delay one is a short delay to guarantee the full closure and seating of the rotary valve before the signal from the resetting of the valve bistable is passed on to set the display bistable. Setting of the display bistable energizes the platen solenoid which forces the sample trapped in the collecting sack into the measuring chamber. The display bistable, upon setting, also supplies a signal to delay two. The time constant of delay two determines the length of time the measured volume information is displayed on the ground glass screen. After the desired display time has elapsed, delay two supplies a signal to set the reset bistable.
Figure 3. Spirometer block diagram
Setting of the reset bistable opens the exhaust valve and energizes the solenoid which empties the measuring chamber syringe. Delay three receives an input upon energization of the reset bistable. This signal is delayed long enough to be certain that the system has been completely emptied and then delivers a signal to reset the reset bistable which closes the exhaust valve and de-energizes the solenoid which emptied the measuring chamber syringe. The output signal of delay three also resets the display bistable which de-energizes the platen solenoid thus allowing the spring loaded platen to return to position shown in Figure 2.

One complete pneumatic and electro-mechanical cycle has been described. The sequence described would measure one full expiratory tidal volume, display this measured volume for a predetermined length of time and finally reset itself ready to make another measurement upon re-energization of the start switch.

Figure 1 shows the complete spirometer. The simplicity of operating it is clear since the controls include only an on-off power switch, a push to read switch, and a knob to adjust the sensitivity of the flow transducer so as to accommodate patients of various sizes.

System Reproducibility and Accuracy

A calibrated glass syringe was placed in the pneumatic circuit of the spirometer in place of the patient. The travel of the syringe was limited by fixed stop-blocks so that the sample size injected to be measured would not vary within the twenty-one test runs for each of the ten different volumes tested. Test volumes delivered were 5, 10, 15, 20, 25, 30, 35, 40, 45, and 50 cm. Delivery flow rates were deliberately varied from very slow to very fast so as to see if varying expiratory flow rates would interfere with accuracy or reproducibility. All measurements were interpolated to
the nearest 0.06 cm.\(^3\)

Table 1 shows the results of the twenty-one test runs. The measured deviation from the volumes delivered for each of the test volumes is found in Table 2.
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<tr>
<th>Test Run</th>
<th>Indicated Volumes[^b]</th>
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<tr>
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</tr>
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<td>21</td>
<td>5.00 10.06 14.94 20.00 25.00 30.00 35.00 40.06 45.00 50.00</td>
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</table>

[^a]: All volumes measured in cm.³

[^b]: All measurements to the nearest 0.06 cm.³
Table 2. Deviation from delivered test volumes

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<th>6</th>
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<td>-0.06</td>
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<td>0.00</td>
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\(^{a}\)All volumes measured in cm.\(^3\)

\(^{b}\)Reported figures are test volumes delivered minus volumes indicated by spirometer.
Table 2. (Continued)

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<td>-0.12</td>
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a Deviation from delivered test volumes
b Deviations of indicated volumes from test volumes delivered
Table 2. (Continued)

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<th>Test Run</th>
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<th>21</th>
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<th>S = Sample Standard Error $\times 10^{-2}$</th>
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*Deviations from delivered test volumes*[^a]

[^a]: $X = \text{Mean}$, $S = \text{Sample Standard Error } \times 10^{-2}$.
STATISTICAL ANALYSIS OF SPIROMETER DATA

Setting of Tolerance Limits Under Assumption of Normality (7)

Sample calculations for delivered volume of 10 cm.$^3$

Tolerance limits $L_1$ and $L_2$ such that the probability is $\beta$ that at least $\gamma$ of the population falls between $L_1$ and $L_2$ are given by the following:

$$L_1 = \overline{X} - \lambda s$$
$$L_2 = \overline{X} + \lambda s$$

$X$ = deviation from the volume delivered to the spirometer

$\overline{X}$ = mean of deviation values

$s$ = Sample standard error

$n$ = number of samples

$\gamma = 0.99$

$\beta = 0.95$

$$\lambda = \left( \frac{n-1}{\chi^2_{n-1,\beta}} \right)^{0.5}$$

$\chi^2_{n-1,\beta}$ = value of chi square with $n-1$ degrees of freedom which will be exceeded $\beta$ of the times.

$r$ = a number such that:

$$\frac{1}{\sqrt{n}} + r \int N(0,1) = \gamma$$

$$\frac{1}{\sqrt{n}} - r$$
\[ N(0,1) = \text{value from a table of normal distribution with a mean value of zero, } \pm \text{ one standard deviation.} \]

\[ \sum x = -12 \times 10^{-2} \]

\[ (\sum x)^2 = 1.44 \times 10^{-2} \]

\[ \sum x^2 = 3.60 \times 10^{-2} \]

\[ \bar{x} = -\frac{12 \times 10^{-2}}{21} \]

\[ \bar{x} = 0.5714 \times 10^{-2} \]

\[ s^2 = \text{sample variance} \]

\[ s^2 = \frac{\sum x^2}{n-1} \]

where \[ \sum x^2 = \sum x^2 - \frac{(\sum x)^2}{n} \]

\[ \sum x^2 = 3.60 \times 10^{-2} - \frac{1.44 \times 10^{-2}}{21} \]

\[ \sum x^2 = 3.5314 \times 10^{-2} \]

\[ s^2 = \frac{3.5314 \times 10^{-2}}{20} \]

\[ s^2 = 0.17657 \times 10^{-2} \]

\[ s = \text{sample standard error} \]
\[ s = 4.20202 \times 10^{-2} \]
\[ \frac{1}{\sqrt{21}} \cong 0.218 \]

Find \( r \) for the following equation

\[ \frac{1}{\sqrt{21}} + r \int N(0,1) = \gamma = 0.99 \]
\[ \frac{1}{\sqrt{21}} - r \]

Using the preceding integral, by successive approximations choose

\( r = 2.58 \)

\[
\begin{array}{cccc}
2.80 & 0.49086 & 0.49744 & \text{table values} \\
-2.36 & 0.98830 & 0.98830 & \\
\end{array}
\]

\( r = 2.70 \)

\[
\begin{array}{cccc}
2.98 & 0.49343 & 0.49856 & \\
-2.48 & 0.99199 & 0.99199 & \\
\end{array}
\]

\( r = 2.64 \)

\[
\begin{array}{cccc}
2.86 & 0.49224 & 0.49788 & \\
-2.42 & 0.99012 & 0.99012 & \\
\end{array}
\]
When \( r \) equals 2.64, \( \gamma \) approaches very closely its desired value of 0.99. Therefore, the value to be used in the following calculations will be 2.64.

From a table of chi square, the \( \chi^2_{n-1, \beta} \) \((\chi^2_{20, 95}\) value equals 10.851.

Find \( \lambda \) from the following equation:

\[
\lambda = \left( \frac{\chi^2_{n-1, \beta}}{\chi^2_{n-1, \beta}} \right)^{r/2}
\]

\[
\lambda = \left( \frac{20}{10.851} \right)^{2.64}
\]

\( \lambda = 3.5851 \)

Compute the limits \( L_1 \) and \( L_2 \)

\[
L_1 = \bar{x} - \lambda s
\]
\[
L_2 = \bar{x} + \lambda s
\]

\[
L_1 = \left[ (-0.5714) - \left( 3.5851 \cdot 4.2020 \right) \right] \times 10^{-2}
\]

\[
L_1 = -15.6360 \times 10^{-2}
\]

\[
L_1 = -0.1564
\]
\[ L_2 = \left[ (-0.5714) + \left( \frac{3.5851}{4.2020} \right) \right] \times 10^{-4} \]

\[ L_2 = +14.4932 \times 10^{-2} \]

\[ L_2 = +0.1449 \]

In view of the calculations, the following statement may be made of the experimental test:

The probability is 0.95 that 0.99 of the measurements will fall between +0.1449 cm.\(^3\) and -0.1564 cm.\(^3\) of the test volume of 10 cm.\(^3\). Another way of making this statement is to say that the probability is 0.95 that 99 of every 100 measurements will fall between +0.1449 cm.\(^3\) and -0.1564 cm.\(^3\) of the test volume of 10 cm.\(^3\) delivered to the spirometer.

**Summary of statistical results for the surfaces**

The following statements may be made of the experimental tests:

The probability is 0.95 that 0.99 of the measurements will fall between +0.1605 cm.\(^3\) and -0.1150 cm.\(^3\) if the specific volume actually delivered to the spirometer is 5 cm.\(^3\).

The probability is 0.95 that 0.99 of the measurements will fall between +0.1449 cm.\(^3\) and -0.1564 cm.\(^3\) if the specific volume actually delivered to the spirometer is 10 cm.\(^3\).

The probability is 0.95 that 0.99 of the measurements will fall between +0.0987 cm.\(^3\) and -0.1215 cm.\(^3\) if the specific volume actually delivered to the spirometer is 15 cm.\(^3\).

The probability is 0.95 that 0.99 of the measurements will fall between +0.1201 cm.\(^3\) and -0.1487 cm.\(^3\) if the specific volume actually delivered to the spirometer is 20 cm.\(^3\).

The probability is 0.95 that 0.99 of the measurements will fall between +0.0842 cm.\(^3\) and -0.1298 cm.\(^3\) if the specific volume actually delivered to the spirometer is 25 cm.\(^3\).
The probability is 0.95 that 0.99 of the measurements will fall between +0.1287 cm.\(^3\) and -0.1402 cm.\(^3\) if the specific volume actually delivered to the spirometer is 30 cm.\(^3\).

The probability is 0.95 that 0.99 of the measurements will fall between +0.0686 cm.\(^3\) and -0.0857 cm.\(^3\) if the specific volume actually delivered to the spirometer is 35 cm.\(^3\).

The probability is 0.95 that 0.99 of the measurements will fall between +0.1168 cm.\(^3\) and -0.0825 cm.\(^3\) if the specific volume actually delivered to the spirometer is 40 cm.\(^3\).

The probability is 0.95 that 0.99 of the measurements will fall between +0.1015 cm.\(^3\) and -0.1387 cm.\(^3\) if the specific volume actually delivered to the spirometer is 45 cm.\(^3\).

The probability is 0.95 that 0.99 of the measurements will fall between +0.1774 cm.\(^3\) and -0.3031 cm.\(^3\) if the specific volume actually delivered to the spirometer is 50 cm.\(^3\).
DISCUSSION OF SPIROMETER

From Table 2 it can be seen that the greatest deviation from actual volume delivered to the spirometer to measured volume occurred at the 50 cm.$^3$ volume. In tracing back through the system for the nearly doubled error in comparison to other volumes it was found that the collection sack was too small to accept the full 50 cm.$^3$ volume without raising delivery pressure above the normal 2 to 3 mm. H$_2$O operating pressure. Compressibility of the gas in the delivery line and internal plumbing of the spirometer accounts for the reduced volumes measured by the spirometer. If the total delivered volume to be measured by the spirometer is kept between 5 and 45 cm.$^3$ one may make the following concise statement about the performance of this specialized measuring device: One may have a 0.95 confidence that 99 of every 100 measurements made by the spirometer will be within ± 0.16 cm.$^3$ of the actual volume of gas delivered for measurement.

The spirometer has been successfully used to measure the tidal volumes of a number of neonates suffering from respiratory distress syndrome. The spirometer has been easy to operate and its reliability has been excellent.
VOLUME CONTROLLED ASSISTER-CONTROLLER

Introduction

Dr. David L. Carlson, in his thesis, *Engineering Aspects of Neonatal Respiratory Augmentation* (3), has clearly stated the design requirements for a respirator capable of assisting the respiratory efforts of neonates by using intermittent positive pressure. He has designed and constructed three respiratory augmentors following the design criteria established by him. These models have been successfully tested in clinical situations during the last 4 years. Adequate clinical experience has now been gained using the Carlson respirators to verify the soundness of his design criteria.

In review, these design criteria are:

1. A satisfactory method of delivering the output of the respirator to the patient. In other words, a satisfactory patient-machine interface which may be left in place 24 to 72 hours without danger to the patient.
2. The system must be able to accurately and reliably sense the onset of inspiration.
3. Ability to provide controlled respiration if this should become necessary or be deemed desirable by the attending physician.
4. Provide an audible alarm should the patient become apneic and then provide a preset forced rate of respiration.
5. Ability to deliver a predetermined volume to the patient at a constant flow rate of 75 cm.\(^3\) per second.

Mr. J. Ben Buck, D.T. and Mr. James E. Triplett have collaborated with the author to develop a special nasal mask for the patient-machine interface. The mask has been cemented to the infant's nose using surgical (colostomy bag) cement and left for periods in excess of 72 hours, then re-cemented and left in place for an additional 48 hours. No damage to the infant's nose or tissue has been noted in any case.
Figure 4 shows the Buck nasal mask used with the respirator described in this study.

The Arp-Varnum respirator described in this study utilizes a negative pressure sensing switch, which has been designed to reliably trigger on a negative pressure of 0.5 mm. H₂O.

Artifact transient negative pressures of 12 cm. H₂O are rejected by this switch and do not cause false triggering of the respirator. See Figure 5. However, if 0.1 cm³ of air is inhaled by the patient the required 0.5 mm. H₂O negative pressure is secured and the respirator is immediately switched on. Gas begins to flow to the patient not more than 20 ms. after onset of inspiration.

Controlled respiration may be supplied to the patient by the respirator simply by setting the controlled rate desired. Controlled rate may vary from zero where the respirator is triggered by the patient's inspiratory efforts to 170 per minute.

The respirator described in this study does not have an audible alarm, as such, to signal attending personnel should the patient become apneic nor does it automatically cycle at a preset rate should the patient become apneic. Experience gained during clinical use of the respirator has shown that the attending personnel will be acutely aware of the "deafening silence" should the machine falter or stop for any reason. The machine can then be manually switched to the desired controlled rate. In addition, loitering down the hall or absence from the treatment area by attending personnel should not be allowed for any reason. Therefore, no alarm is needed. Experience has also shown that attending personnel are not able to discern, even with an alarm, whether the respirator is being triggered by an automatic timing function built into the respirator to deliver gas at a preset rate in case the patient becomes
Figure 4. Buck nasal mask
Figure 5. Respirator's ability to reject transient negative pressures 12 cm. $H_2O$
apneic. The respirator may fail to be tripped by the patient for four reasons. First, the patient may not be breathing spontaneously, in other words he may be apneic. Second, the patient may be attempting inhalation but not moving air into his lungs because the airway is not patent. Third, a leak may have developed in the pneumatic circuitry connecting patient and machine. And finally, the negative pressure sensing switch may not be functioning properly. Only in the latter case would the automatic cycling of the respirator have any advantage to offer the patient. In this event, the machine could manually be switched over to the desired controlled rate. Attending personnel automatically assume that the patient is being adequately ventilated as long as the machine is running even when the alarm indicating forced cycling of the machine is audibly signalling. The author has observed the occurrence of this obvious lack of understanding of the system and its functions on four different occasions. The author strongly believes that reliance on an automatic cycling system even with audible alarms presents a clear and definite danger to the patient unless a person is always present during treatment who fully understands the operation of the respirator and the alarm system. Doctors and nurses should not be expected to completely understand the system. A respirator is not used frequently enough to be sure that all attending personnel are proficient in the use of the equipment.

The Arp-Varnum respirator described in this paper will deliver an adjustable preset volume of gas (from 5 cm.$^3$ to 1500 cm.$^3$), and mix any two gases to any concentration desired. Flow rates to the patient are continuously adjustable from 0 to 20 liters per minute (0 to 333 cm.$^3$ per second.) Observations of delivery waveforms during clinical use of the respirator have indicated that a constant flow rate of 75 cm.$^3$ per second is many times not adequate to
satisfy the infant and to secure the greatest reduction of the work done in breathing. It is not at all uncommon to need an average flow rate in excess of 100 cm.\(^3\) per second. A fixed, constant flow rate as suggested by Dr. Carlson does not supply a flow of gas to the patient at a high enough rate in the beginning phase of assistance to relieve the patient of as much work in breathing as is possible by using a combination of the reverse ramp flow and constant flow waveforms. The respirator in this study begins flow to the patient by supplying the patient for approximately 15% of the total inspiratory time using the reverse ramp flow waveform and then maintains a constant flow waveform for the remainder of the inspiratory cycle.

The patient must pull a slight negative pressure (0.5 mm. H\(_2\)O) at the beginning of the inspiratory phase in order to turn the respirator on. However, in order to eliminate most of the work being done by the infant during inspiration the pressure in the thorax and lungs must not be allowed to remain negative. Therefore, after the respirator is turned on, air flow must be great enough to keep the length of time that the thorax and lungs are at a negative pressure to a minimum. In general, gas flow to the infant should begin not later than 25 ms. after onset of inspiration. Since the thorax and lungs are at a negative pressure until the flow of gas has caught up with the demand it is imperative that the lag be made up as quickly as possible to maximize the assistance provided by the respirator.

Figure 6 shows the record of nasal pressures for a premature infant in respiratory distress being treated by a volume controlled assister using the constant flow waveform. Figure 7 shows the same infant being treated by the Arp-Varnum volume controlled assister using the combined reverse ramp and constant flow waveforms. The infant did considerably less work as shown by the much smaller area
Figure 6. Nasal pressures using constant flow waveform
Figure 7. Nasal pressures using a combination of reverse ramp and constant flow waveforms (Arp-Varnum respirator)
under the baseline when assisted by the combined reverse ramp and constant flow waveforms.

System Description

For descriptive purposes, the respirator may be divided into two separate sections: one, the pneumatic drive and delivery section, and the other, the sensing and electronic control section. Figure 8 shows the complete respirator. Figure 9 shows the respirator pneumatic block diagram and Figure 10 shows the respirator electronic block diagram. Note that the pneumatic circuit for the respirator is actually a bifurcation; the input side for delivery of gas from the respirator to the patient and the exhalation side. The inflatable exhaust valve at the end of the Buck nasal mask, seen in Figure 4, is normally closed. The respirator begins a delivery cycle with the patient tripping the negative pressure switch by pulling a negative pressure on the delivery line of 0.5 mm. H₂O. For the sake of illustration, assume the pistons in cylinders one and two are at the position shown in Figure 9 at the beginning of the inspiratory cycle. Each time the respirator is tripped on a control line delivers high pressure (30 to 50 cm. H₂O) gas to the inflatable exhaust valve located at the end of the Buck nasal mask to make sure that the gas to be delivered to the patient by the respirator does not escape out of the exhaust part. At the end of the delivery stroke the exhaust valve control line is quickly dropped to atmospheric pressure, therefore, the pressure in the delivery line to the patient pops the exhaust valve open so that the patient may freely exhale from the open exhaust part. This sequence positively eliminates any chance of the inflatable valve sticking shut and impeding expiration. The tripping of the negative pressure switch energizes and opens valves one and three. Driving gas, usually O₂ at a pressure of 50 psi, flows into
Figure 8. Arp-Varnum volume limited respirator
Figure 9. Respirator pneumatic block diagram
AUTOMATIC SIGH TIMING CKT.

1. Emitter

2. Emitter Follower

3. Negative Pressure Switch

4. Manual Trigger Switch

1. Right Limit Switch

2. Left Limit Switch

Valve #1

Valve #2

Valve #3

Valve #4

X-Ray Trigger

TO X-RAY MACHINE

NOTE:

S1 RIGHT LIMIT SWITCH
S2 LEFT LIMIT SWITCH
S3 NEG. PRESSURE SWITCH
S4 MANUAL TRIGGER SWITCH

Figure 10. Respirator electrical block diagram
the left end of the driving cylinder one, forcing the piston to move from left to right. The driving piston is attached to the driven piston contained in cylinder two by a connecting rod which passes through seals at the right end of cylinder two and the left end of cylinder one. As the two pistons move from left to right the $O_2$ which moved the pistons from right to left during the previous delivery stroke and which still remains in cylinder one is forced out of cylinder one through the open valve three. At the same time the gas from the auxiliary input which was drawn into the right side of cylinder two through the one-way valve six during the previous delivery stroke is forced out through the one-way flow valve seven where it is mixed with the $O_2$ being expelled from cylinder one and delivered to the patient. As the piston in cylinder two moves from left to right a new supply of gas for the next stroke is drawn into the left end of cylinder two through the one-way valve five. Knowing the concentrations of the driving gas and the gas supplied to the auxiliary input as well as the volumes of cylinders one and two makes it possible to deliver a uniform and known concentration of gas to the patient regardless of the pressure variations which may occur in the delivery line. The volume of gas delivered to the patient is varied by moving end plugs into both cylinders to limit the distance that the pistons may travel. Limit switches located in the end plugs of cylinder two sense the approach of the pistons near the end of travel. The limit switch at the right end of cylinder two de-energizes valves one and two. The limit switches are adjusted so as to start shut-down of the system before the pistons come to rest against the end plugs thus preventing a transient shock wave from reaching the patient. Inertia of the moving piston and accumulated driving gas in cylinder one causes the piston to continue to the end of travel. Complete closure of the valves coincides with the end of travel of the pistons,
giving a smooth shut-down at end of the delivery stroke. Upon shut-down, valve one exhausts the left end of cylinder one to atmospheric pressure. The next time the machine is tripped on, valves two and four are energized and opened thus causing the pistons to move from right to left. Gas from the auxiliary input is drawn into cylinder two through the one-way valve six and delivered to the patient through the one-way valve eight. As in the previous cycle, gas from the two cylinders is again mixed and delivered to the patient. A limit switch located in the left end plug of cylinder two again shuts the system down near its end of travel. Delivery pressure is monitored on a gage on the front panel of the respirator. Maximum delivery pressure to the patient is selected by adjusting the safety pop-off valve also located on the front panel.

The electrical block diagram in Figure 10 shows the limit switches in the positions in which they are found when the pistons are at the left end of the cylinders as shown in Figure 9. When the patient trips the negative pressure switch upon the onset of inspiration bistable one is set. The emitter follower driven by bistable one energizes valves one and three starting the delivery cycle described in the discussion of the pneumatic circuitry. The pistons, upon approaching the end of travel to the right, close limit switch one shutting the system down. The next time the negative pressure switch is tripped by the patient bistable two is set. The emitter follower two driven by bistable two energizes valves two and four starting another delivery cycle. The pistons, upon nearing the end of travel to the left again closes limit switch two thus completing the end of one complete mechanical cycle and two delivery cycles to the patient. As seen in Figure 10, the respirator may be triggered by the patient, a manual push button switch, a timing circuit for controlled rate triggering, or an
automatic sigh timing circuit.

The function of the automatic sigh timing circuit is to provide a double volume delivery to the patient at regular intervals, thus simulating the natural physiologic sigh.

Power is provided by an unregulated power supply. Two voltages are used, -12 volts for the electronic circuitry and actuation of the valves and +2.5 volts bias for the transistor circuitry. This arrangement allows the system to be operated from the usual 117 volts AC power line or from a 12 volts DC source as one would find in an automobile or any emergency vehicle. The +2.5 volts bias source is nothing more than two common D size flashlight cells in series. A zener diode provides the necessary reference for securing the +2.5 volts from the 3 volts delivered by the two D size cells in series. Current requirements from the bias supply is so small that one set of cells will operate the system continuously for over a week. The system is, therefore, ideally suited for use either in the hospital and operating on a standard 117 volts AC line or in an emergency vehicle and powered by batteries.

Transistor circuitry is used throughout and is found on one plug-in type phenolic board. The unit has been successfully tested between 0° C. to 55° C. without erratic operation. The system is so tolerant of voltage fluctuations (-8 volts to -15 volts; +2 volts to +4.5 volts) that it is not necessary to provide any type of regulation for the power supply to secure system reliability.
AUTOMATIC X-RAY TRIGGER IN RESPIRATOR

Serial radiographs are used in an attempt to determine the extensiveness of atelectasis or the possibility of the patient having a tracheo-esophageal fistula and to follow the progress of the patient suffering from respiratory distress.

The X-ray technician attempts to trip the X-ray machine at peak inflation of the lungs. Infants are incapable of the cooperation desired, that is, inhaling and holding the breath until after the exposure has been made. This presents quite a challenge to the X-ray technician, for he must make the exposure at peak inflation of the lungs and without delay.

Most infants breathe between 30 and 120 times a minute. Uniformity in the degree of inflation of the lungs from one radiograph to another is very rare and therefore the radiographs are not uniform. This non-uniformity makes it difficult for a radiologist to always be certain of the degree of change in the patient's condition when comparing one film with another.

A simple solution to this problem has been found. A trigger circuit has been added to the respirator so that the X-ray machine will be tripped immediately following delivery of a tidal volume. See Figure 10. Unless the tidal volume delivered to the patient by the respirator is deliberately changed by the operator, uniform inflation of the lungs is guaranteed from one radiograph to another.

Changes in the appearance of serial radiographs can now be read with assurance since a change in density is most assuredly caused by a change in the patient's condition. Obviously, this is true only if the same type of film receives the same exposure time and radiation level along with uniform darkroom developing times and temperature. These latter
items are routinely held to close tolerances and do not enter into the discussion except as an academic issue.
LABORATORY TESTING OF THE RESPIRATOR

The respirator was first tested on anesthetized rabbits. Three cm. of 5% Xylocaine was administered locally to the trachea and femoral artery regions. Rabbits were chosen to simulate newborn infants because of striking similarities in their respiratory patterns. The delivery line of the respirator was attached to a Buck nasal mask with the mask in turn fitted to a small bore tube adapter. The tube was attached to the rabbits by means of a tracheotomy and finally, the adapter fitted to the tube. Total dead space in the system was increased about 0.75 cm.

Test rabbit one was a 3 pound 4 ounce white rabbit. Blood gas analysis was made on blood drawn from the femoral artery at 9:07 A.M., August 11, 1965. The Astrup method gave the following baseline for the rabbit with spontaneous respiration of room air:

\[
\begin{align*}
\text{pH} & \quad 7.440 \\
\text{S.B.} & \quad 18.0 \text{ mEq./liter} \\
\text{B.B.} & \quad 39.0 \text{ mEq./liter} \\
\text{P}_a \text{CO}_2 & \quad 22.0 \text{ mm. Hg.} \\
\text{B.E.} & \quad 7.9 \text{ mEq./liter}
\end{align*}
\]

The rabbit's blood pressure was a uniform 120/65 mm. Hg. Respiration rate was 100 per minute indicating some excitement. Peak expired CO\(_2\), as measured with a Beckman-Spinco LB-1 gas analyzer, was 2.5%.

Figure 11 shows the femoral artery pressure for rabbit one during spontaneous respiration. Figure 12 shows the expired CO\(_2\) during spontaneous respiration.

The laboratory equipment setup for tests of the respirator is shown in Figure 13. The rabbit is seen in the center foreground, a Sanborn strip-chart recorder, a Beckman-Spinco LB-1 gas analyzer with another strip-chart recorder, the Arp-

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1Childrens Hospital of Los Angeles, 4614 Sunset Boulevard, Los Angeles, California
Figure 11. Test rabbit 1, femoral artery pressures (spontaneous respiration)
Figure 12. Test rabbit 1, expired CO₂ (spontaneous respiration)
Figure 13. Experimental laboratory and equipment
Varnum volume controlled respirator with an "H" size tank of oxygen behind it to supply the driving power for the respirator, the Bird respirator and Bird anesthesia assist­er controller, and finally and anesthesia machine with flow meters and gas bottles. A Fluotec vaporizer for delivering Fluothane at a known concentration is also attached to this unit.

An inhalation therapist from the out-patient clinic of the Childrens Hospital of Los Angeles, Los Angeles, California was asked to set up the Bird respirator to assist the rabbit's breathing using 40% O₂. The author believes that this procedure removed as much bias from the setup and testing as was possible. The flow rate was adjusted by the inhala­tion therapist to approximately 8 liter per minute (133 cm.³/ sec.) and a cut-off pressure (gage pressure at the output of the Bird respirator) of 20 cm. H₂O.

Figure 14 shows the rabbit's femoral artery blood pressures while being assisted by the Bird respirator. Note the severe oscillations in the recorded pressures. Equally erratic breathing patterns are evident in the tracings of the expired CO₂ seen in Figure 15.

After 1 hour and 30 minutes on the Bird respirator the arterial blood pressure tracing seen in Figure 16 shows larger oscillations in pressure. The expired CO₂ record at this time, as seen in Figure 17, shows the rabbit experi­encing some difficulty in breathing.

Figure 18 shows the femoral artery pressure tracing as the rabbit experienced a cardiac arrest. The rabbit had been ventilated by the Bird respirator operating in the assist mode for 1 hour and 45 minutes. 40% O₂ was delivered

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1Fraser Sweatman, Inc., 780 Oliver Street, North Tonowanda, N. Y.
Figure 14. Test rabbit 1, femoral artery pressures (on Bird respirator)
Figure 15. Test rabbit 1, expired CO₂ (on Bird respirator)
Figure 16. Test rabbit 1, femoral artery pressures (on Bird respirator)
Figure 17. Test rabbit 1, expired CO₂ (on Bird respirator)
Figure 18. Test rabbit 1, femoral artery pressures (on Bird respirator)
to the rabbit at a flow rate of approximately 8 liters per minute (133 cm.\(^3\)/sec.) to a shut-down gage pressure of 20 cm. H\(_2\)O measured at the output of the respirator. Figure 19 shows the rabbit experiencing continued and more severe respiratory difficulty. Shortly after the rabbit experienced the cardiac arrest, spontaneous respiratory efforts also stopped. An arterial blood sample was drawn immediately. The pH was found to be 7.00 and the \(P_aCO_2\) 55 mm. Hg. External cardiac massage was started after a few seconds of arrest. The heart started after light massage as seen in Figure 18 and respiration resumed in an erratic manner. At this point it was decided to remove the respirator and to allow the rabbit to breathe spontaneously.

The Arp-Varnum respirator was connected to test rabbit one after being allowed to breathe room air spontaneously for 2 hours. The flow rate of this respirator was adjusted to match the flow rate of the Bird respirator. The tidal volume delivered each time the rabbit tripped the machine was adjusted so that the maximum delivery pressure at the end of each delivery stroke matched the 20 cm. H\(_2\)O pressure used with the Bird respirator. Therefore, shut-down gage pressures measured at the outputs of both of the machines was the same.

The rabbit's femoral artery pressure and \(CO_2\) traces appeared to be like those observed before the Bird respirator was put into operation at the beginning of the test. These traces can be seen in Figures 11 and 12.

A blood gas analysis was made to determine a starting point or baseline before attaching the Arp-Varnum respirator. The Astrup studies gave the following values:

- \(pH\) 7.46
- S.B. 17.0 mEq./liter
- B.B. 36.2 mEq./liter
- \(P_aCO_2\) 19.0 mm. Hg.
- B.E. 9.1 mEq./liter

The rabbit's blood pressure was again a uniform 120/65 mm. Hg. Respiration rate was between 90 and 100
Figure 19. Test rabbit 1, expired CO$_2$ (on Bird respirator)
breaths per minute indicating some excitement. Peak expired CO₂ was about 2.5%.

Figure 20 shows the rabbit's femoral artery pressures while being assisted by the Arp-Varnum respirator. Note the even and almost wholly undisturbed level of the tracing when compared to the tracing in Figure 9, obtained while the rabbit was breathing spontaneously without respiratory assistance. There is a startling contrast between Figure 20 which shows uniform femoral artery pressures while the rabbit was being assisted on the Arp-Varnum respirator and Figure 14 which shows oscillatory surging and subsiding of the femoral artery pressures while the rabbit was being assisted on the Bird respirator. Figure 20 also shows a second recording channel's trace above the pressure trace. Each deflection of the second trace indicates the end of delivery of a tidal volume to the rabbit. Peak delivery pressure was reached immediately before each mark. Near the center of the upper tracing two deliveries were made in very rapid succession. This was a timed and sequenced operation to sigh the patient. Even at this event no depression or disturbance of the arterial pressure can be seen in the bottom tracing. This is probably true because the pressure of the delivery line to the patient is dropped to atmospheric pressure immediately after the delivery of a tidal volume. In this way, the respirator can quickly do the job of assisting the inspiratory phase and then get out of the system before circulatory embarrassment can occur. Figure 21 shows the tracing for the expired CO₂ with the chart speed reduced to show the result of the evenly spaced automatic sighs spaced 2 minutes apart. A second sigh is produced 8 seconds after the first. Each sigh is produced by delivering two tidal volumes before the patient can exhale the first delivered volume. The forced sigh is intended to simulate the natural physiological sigh which usually occurs about
Figure 20. Test rabbit 1, femoral artery pressures (on Arp-Varnum respirator)
Figure 21. Test rabbit 1, expired CO$_2$ (on Arp-Varnum respirator)
every two to three minutes.

Arterial blood gas analysis by the Astrup method after the rabbit had been assisted by the Arp-Varnum respirator delivering 40% oxygen for 3 hours and 30 minutes showed the following:

\[
\begin{align*}
\text{pH} & \quad 7.42 \\
\text{S.B.} & \quad 17.0 \text{ mEq./liter} \\
\text{B.B.} & \quad 36.2 \text{ mEq./liter} \\
\text{P}_a\text{CO}_2 & \quad 22.5 \text{ mm. Hg.} \\
\text{B.E.} & \quad -8.9 \text{ mEq./liter}
\end{align*}
\]

The rabbit's blood pressure remained a uniform 120/65 mm. Hg. Respiration rate was between 55 and 60 breaths per minute. The respiration rate is well within the normal range expected for a rabbit and indicates that the rabbit was less excited than at the beginning of assistance when the rabbit was breathing between 90 and 100 times per minute. Peak expired CO\(_2\) remained normal at about 2.5%.

Figure 22 shows the rabbit's femoral artery pressure while delivering 100% oxygen at the same flow rate and peak pressure used throughout this study. The rabbit had been on the respirator 3 hours and 30 minutes receiving 40% oxygen then the delivered concentration was changed to 100% oxygen for 16 minutes. The left half of the expired CO\(_2\) tracing seen in Figure 23 shows the level of expired CO\(_2\) and the respiration rate of the rabbit receiving 100% oxygen for 16 minutes. The right half of the tracing shows an increase in respiration rate three breaths after the delivered oxygen concentration was reduced to 40%. The three cycles representing the three breaths which separates the left and right sides of the tracing clearly shows how rapidly the rabbit sensed the change in concentration and was able to readjust his rate to maintain an oxygen intake commensurate with his needs. A similar shift in rate is observed if the tidal volume delivered to the rabbit is lowered by one or two cm.\(^3\) This same shift in rate has been observed many times during assistance of infants suffering
Figure 22. Test rabbit 1, femoral artery pressures (on Arp-Varnum respirator)
Figure 23. Test rabbit 1, expired CO$_2$ (on Arp-Varnum respirator)
from respiratory distress.

Summary And Discussion Of The Laboratory Tests

The blood gas analyses provide a great deal of information concerning the adequacy of ventilation of the rabbit. The test rabbit, while breathing room air without assistance from a respirator, had a blood gas analysis as follows:

- pH 7.440
- S.B. 18.0 mEq./liter
- B.B. 39.0 mEq./liter
- \( P_{aCO_2} \) 22.0 mm. Hg.
- B.E. -7.9 mEq./liter

The Bird respirator, set up and adjusted by the hospital's inhalation therapist, assisted the rabbit for 1 hour and 45 minutes when the rabbit experienced a cardiac and pulmonary arrest. A blood sample was drawn within seconds of the arrest because the arrest had been anticipated in view of the previous tracings of the femoral artery pressures. Only the pH and \( P_{aCO_2} \) was checked at this time. The analysis showed the pH to be 7.00 and the \( P_{aCO_2} \) to be 55.0 mm. Hg.

The rabbit was removed from the Bird respirator and allowed to breathe room air spontaneously for 2 hours. A new arterial blood gas analysis was run to determine the rabbit's condition and to establish a new baseline from which to start ventilating the rabbit with the Arp-Varnum respirator.

The results of the analysis are reviewed below:

- pH 7.46
- S.B. 17.0 mEq./liter
- B.B. 36.2 mEq./liter
- \( P_{aCO_2} \) 19.0 mm. Hg.
- B.E. -9.1 mEq./liter

These values compare closely with those found before the Bird respirator was used to assist the rabbit's respiration. It is assumed that the cardiac and pulmonary arrest the rabbit experienced while being assisted by the Bird respirator had no lasting effects. Therefore the Arp-Varnum
respirator was used to assist the rabbit's respiration. The same flow rate and peak pressure was used for both respirators.

A review of the blood gas analysis after the rabbit had been assisted by the Arp-Varnum respirator for 3 hours and 30 minutes appear below.

<table>
<thead>
<tr>
<th>pH</th>
<th>S.B.</th>
<th>Pa CO2</th>
<th>B.B.</th>
<th>B.E.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.42</td>
<td>17.0 mEq./liter</td>
<td>22.5 mm. Hg.</td>
<td>36.2 mEq./liter</td>
<td>-8.9 mEq./liter</td>
</tr>
</tbody>
</table>

The above values are very close to those found for the rabbit before being assisted by either respirator. Initial blood gas analysis values at the beginning of the test were:

<table>
<thead>
<tr>
<th>pH</th>
<th>S.B.</th>
<th>Pa CO2</th>
<th>B.B.</th>
<th>B.E.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.440</td>
<td>18.0 mEq./liter</td>
<td>22.0 mm. Hg.</td>
<td>39.0 mEq./liter</td>
<td>-7.9 mEq./liter</td>
</tr>
</tbody>
</table>

Both of the respirators were delivering gas to the patient at the same flow rate and to the same peak pressure, therefore it appears that the respirator's start-up time, delivery waveform, and shut-down characteristics play an extremely important role in determining the degree of circulatory embarrassment caused by intermittent positive pressure assistance of respiration. Avery points out that intermittent positive pressure respiration can produce deleterious effects in the event of shock or any other condition which may tend to impede or interfere with the infant's peripheral circulatory adjustments (2). The newborn infant's pulmonary blood pressure is normally low. Therefore, pressures generated in the thorax and lungs during intermittent positive pressure respiration may easily exceed the critical closing pressure of the alveolar capillaries. This critical closing pressure, according to Carlson, may be as low as 5 or 6 mm. Hg. (3). Collapse of alveolar capillaries would cause shunting of blood away from areas of possible gas exchange. Therefore, it is very probable
that the use of intermittent positive pressure respiration, unless low pressures (15 to 20 cm. H₂O) are used and then delivery waveform is carefully designed for the requirements of these infants, may actually reduce the gas exchange in the lungs. The author believes that one must also consider the bidirectional and patent shunts which are active in the infant during the first few days of life. There is a very good possibility that these patent shunts may cause the critical closing pressures of the alveolar capillaries to be much lower than the 5 or 6 mm. Hg. pressures described by Carlson. The drastic changes in femoral artery pressures during the positive pressure phase of delivery using the Bird respirator, even at the low 20 cm. H₂O peak delivery pressure, supports the author's contention that a proper delivery waveform as well as low delivery pressures are essential for successful treatment of respiratory distress in the newborn. See Figures 14, 16, and 18. Mushin et al. contend that once the alveoli have expanded during inspiration it is unlikely that important additional gaseous exchange occurs (8). Even with the drastically reduced compliance found in infants suffering from respiratory distress it should not be necessary to use pressures above 25-30 cm. H₂O to inflate most of the alveoli. 10 to 18 cm. H₂O pressure has been adequate for most of the infants treated to date. Only once were greater delivery pressures used, and in this case the infant did not show any improvement and expired a few hours after assistance was started. Delivery of smaller tidal volumes with the attendant lower delivery pressures may be far more expedient than large volumes at high pressures. The infant will adjust his breathing rate upward to maintain an adequate minute volume. See Figure 23. Blood flow will remain adequate in the pulmonary bed and greater minute gas exchange will result. Finally, to further support the author's appeal to use lower delivered tidal volumes and
lower peak delivery pressures when treating the distressed infant, Dawes says that, "The pulmonary circulation is very labile in the fetus and newborn, asphyxia causing intense vasoconstriction. The possibility thus arises that pulmonary blood flow can be reduced under certain conditions after birth, to such an extent as to limit $O_2$ uptake. This may be the explanation for the progressive deterioration in infants dying of the respiratory distress syndrome (9)."
TEMPERATURE SENSOR-CONTROLLER

Introduction

Avery et al. in a review of the respiratory physiology in a newborn infant say that, "The metabolism per kilogram body weight in the infant is about double of that of the adult; lung surface area per unit body weight is estimated to be about the same, thus the infant has less reserve lung surface area to meet added metabolic requirements. A cool environment for the infant results in larger heat losses because of the large surface to volume ratio, and is metabolically costly in that oxygen consumption may double or triple over resting values in a warm or thermally neutral environment. Thus the added effects of cooling, activity, and any pulmonary dysfunction may precipitate respiratory failure with carbon dioxide retention and hypoxia (10)."

In view of this and other research findings it is obvious that in order to be able to treat an infant suffering from respiratory distress out of an incubator it would be absolutely essential to be able to continuously monitor and control the infant's temperature within very close limits.

Commercial temperature indicating and controlling apparatus which are available today are very costly, bulky, and hard to handle and many times not accurate or reliable enough for this application. Therefore, a simple and very accurate direct-reading temperature indicator-controller has been developed. The instrument will give a continuous indication of patient temperature to ± 0.1 degree Fahrenheit from 85 to 105 degrees Fahrenheit. No drift in measured temperature is detectable when ambient temperature varies as much as 60 degrees Fahrenheit. The sensing element may be used as either a rectal or esophagus probe. Temperature range to be held by the controller is selectable and may be held to within ± 1 degree Fahrenheit. In addition, the
controller is equipped with a visual flashing alarm to indicate when the controller is driving whatever heating device is used; upper and lower temperature limit alarms are provided and may be set to sound an audible alarm whenever the measured temperature exceeds the selected limits. The instrument operates on low voltage (18 volts for the control and alarm circuits and 3 volts for the temperature sensing and indicating circuits.) The temperature sensing probe has a relatively high resistance and draws less than 1 ma. current. Self heating of the temperature sensing probe is far less than what one finds in using a thermistor as a sensor.

Thermocouples generate very small potentials which vary in amplitude with temperature. These are commonly used to measure temperature. Their disadvantages are well-known and they have therefore been eliminated from consideration as sensors suitable for routine clinical use.

Thermistors are routinely used as temperature sensors and were seriously considered for use in this application. However, the percentage change in a thermistor's resistance per degree temperature change was not as large as one might want to secure the desired accuracy in temperature read-out. In addition, after considering the relatively large current required for a direct full-scale read-out of temperature in the range of 85 to 105 degrees Fahrenheit and the associated self heating of a thermistor probe it was decided that a new type of temperature sensing device was needed.

A transistor for a temperature sensor

A small transistor was eventually chosen as the sensing element. If this device is used properly an effective lever can be secured to amplify the direct result of temperature change. The leakage current for a transistor approximately doubles for each 10 degrees Centigrade temperature rise. In addition, with zero base current the total collector
leakage current \((I_{ceo})\) for the transistor is approximately \((\beta + 1)\) times the reverse leakage current of the collector \((I_{co})\). "\(\beta\)" is the current amplification factor for the transistor. Therefore, the most sensitive temperature measuring probe should have a high "\(\beta\)" and a high leakage current. The use of the transistor in this thermometer is an attempt to utilize the very characteristics of a transistor which is most concern and least desirable for other types of transistor circuit applications.

The change in resistance of the probe with a change in temperature may be considered a measure of the leakage current for the device. The resistance of a typical thermistor from \(85^\circ\) Fahrenheit to \(105^\circ\) Fahrenheit is 6,000 ohms at \(85^\circ\) F. to 3,600 ohms at \(105^\circ\) F. The resistance changes by a factor of about 1.69. The resistance of the new transistor probe is 6,000 ohms at \(85^\circ\) F. and 400 ohms at \(105^\circ\) F. In this case the resistance changes by a factor of 15.

Since the percentage change in resistance per degree of temperature change is much greater with the transistor than with the thermistor, it becomes obvious that the transistor is a device which may now be used to great advantage in measuring temperature and temperature changes very accurately.

Figure 24 shows the complete temperature sensor-controller. A schematic diagram for the sensing and indicating portion of the instrument is shown in Figure 25. The transistor probe, a Raytheon 782 transistor, which was removed from a hearing aid is shown in the schematic as one leg of a common bridge circuit. A switch, \(S_1\), is the on-off switch for the battery supply. \(S_2\) is the calibration switch which is normally in the position shown in the schematic while temperature measurements are being made. \(S_2\) is switched to remove the transistor from the bridge circuit and to insert a fixed resistor in its place for calibration.
Figure 24. Temperature sensor-controller
Figure 25. Temperature sensor-indicator schematic diagram
purposes. Calibration is achieved by varying the position of the wiper on the calibration potentiometer until the 0-100 μa. meter movement is displaced to a predetermined value called the calibration point. The transistor is switched back into the bridge circuit and the thermometer is ready for use.

A small thermometer as described has been in regular clinical use daily the last three years with the two "D" size flashlight batteries being changed once a year. From this one may have a better feeling for the extremely small amount of current required by the thermometer.

**Temperature regulating and alarm circuits**

Three photo-semiconductors are placed behind slots cut in the meter face of the thermometer. Light from bulbs illuminating the meter face hold the semiconductors in the conducting state. The center photo-semiconductor alternately turns the heaters on and off as the meter hand blocks off the light or exposes the center semiconductor to the light. The semiconductors on either side of the heater control semiconductor serve as lower and upper temperature limit alarms. If the meter hand blocks off light to either of these cells a raucous alarm is sounded to call attending personnel. The alarm may be temporarily turned off by pushing a reset button, however it is impossible to permanently disable or shut off the alarm circuit. The alarm will sound each time the light is shut off from either of the alarm semiconductors. In addition to the audible alarm signalling high or low temperatures alternately flashing red lights are turned on while the heater is on to warn the attending personnel that heat is being applied to warm the infant. Figure 26 shows the block diagram for the temperature regulating and alarm section of the sensor-controller apparatus.
Figure 26. Temperature controller block diagram
The temperature sensor-controller has been used the last three years and has been found to be useful and reliable in all cases.
TILTING BED

Introduction

Conventional bassinets and incubators do not provide convenient access to the infant suffering from respiratory distress. The intensive care required by these patients, routine suctioning, turning to prevent pressure necrosis and accumulation of fluid in the upper lobes of the lungs, and securing serial arterial blood samples and radiographs had proved to be almost impossible.

Thomas et al. made the following comments in a recent paper, "The supine position is notoriously bad for drainage of the upper lobes of the lung. Ideally, respirator patients should be cared for in the lateral or semiprone position and the supine position should be avoided as much as possible. Moreover, they should be turned from one side to the other about once an hour. In practice, however, the maneuver of turning a baby attached to a respirator is not without risk because the endotracheal tube can become dislodged. When this happens, the most ill babies, who are only marginally compensated, quickly develop pallid cyanosis, bradycardia, and cardiac arrest. For this reason, the position was changed rather infrequently when a baby was attached to the respirator and was done only in the presence of a physician who could rapidly oxygenate and reintubate if necessary. The movements associated with the taking of X-ray pictures were also dangerous and were similarly supervised (11)."

Tilting Bed for Clinical Use

Figure 27 shows a tilting bed which, for the past three years, has been used to support the infants who were placed on a respirator for treatment of respiratory distress. The bed consists of a canvas sheet stretched tight within a rectangular frame. This tightly stretched sheet supports
Figure 27. Tilting bed
the infant. The frame is motor driven and is pivoted in the center. It may be turned 90° in either direction from the horizontal position. Four plates attached to the frame provide support for sliding clamps to hold the infant's head and torso. These adjustable clamps are covered with snap-on padded covers to prevent pressure necrosis. It has been found that the infant need not be securely clamped in a fixed position. In actual practice the clamps have had to do little more than support the infant when the frame is tilted to one side or the other. A restraining blanket-like cover, fastened to the rectangular tilting-frame, is placed over the bed to be certain that the infant cannot slip out of the device. The blanket-like cover also serves as an effective heat barrier and reduces body-heat loss. A pocket on the bottom side of the canvas support sheet holds a heating pad which is controlled by the temperature sensor-controller. In this way the patient's temperature is controlled and held constant. The pocket is also used to hold an X-ray film casset for radiographs. The infant need never be removed from the bed during treatment or disturbed in any way even while radiographs are taken. Radiographs are routinely taken while the infant is sleeping. The tubing from the Buck nasal mask to the respirator is secured by a clamp on the rectangular frame so that the infant and tubing remain in a fixed position with respect to each other even when the infant is tilted from side to side. To turn the infant the attending nurse holds a switch in the direction in which she wishes to rotate the infant while a motor driven gear-train slowly rotates the bed until the switch is released. A safety slip-clutch is provided on the pivot point of the bed so that the frame may be quickly rotated to one side by hand should the infant vomit while in the supine position for a radiograph. In this way the chance for aspirating foreign matter may be considerably reduced.
The tilting bed has given the attending physicians and nurses almost unrestricted access to the patient during treatment. Contrary to the general consensus of opinion, respiratory assistance by intermittent positive pressure and the intensive care required by the newborn need not conflict in any way. Clinical use has shown the tilting bed to be a most desirable piece of equipment for treating respiratory distress with a respirator.
REPORT OF CLINICAL APPLICATIONS

A number of babies have been treated for respiratory distress using elements of the system described in this study. Progress notes and blood gas analyses data for three of the six babies treated with the Arp-Varnum respirator are given below.

Baby W.:

This baby had been on a volume controlled respirator delivering 30 cm.$^3$ of 40% O$_2$ in the controlled-respiration mode for about 24 hours. An endotracheal tube served as the connecting interface between patient and machine. The baby was actively fighting the controlled rate during this time. Adjustment of delivery rate and tidal volumes did not improve the baby's acceptance of the machine. After being on the respirator for about 25 hours the baby experienced a cardiac and pulmonary arrest. Muscle tone and color was poor. External cardiac massage was used to regain control of the situation. The baby continued to resist the respirator and color remained very poor. It was decided that the controlling pump was probably doing the infant little good and treatment was discontinued. The infant was allowed to breathe 100% O$_2$ spontaneously for 10 minutes while a Buck nasal mask was fitted to the patient and cemented in place. Respiration appeared very labored with deep retractions and expiratory grunting. Very poor color indicated that the baby must be assisted if it was to survive.

The Arp-Varnum respirator was connected to the nasal mask at 9:00 A.M. and operated in the assist mode. 35 cm.$^3$ of 40% O$_2$ were delivered each time the baby triggered the respirator. Maximum delivery pressure was 21 cm. H$_2$O. 3 minutes after the baby was put on this respirator retractions had stopped. The baby's color was pink. 5 minutes after beginning assistance the baby was sleeping and remained
calm until blood samples were drawn from the heel at 11:30 A.M. 
Blood gas analysis 11:30 A.M. (Astrup Method):
pH 7.25 S.B. 18.2 mEq./liter
B.B. 38.9 mEq./liter PCO₂ 43.5 mm. Hg.
B.E. -6.5 mEq./liter
The final blood gas analysis made on this baby was at
1:30 P.M.
Blood gas analysis 1:30 P.M. (Astrup Method):
pH 7.41 S.B. 24.2 mEq./liter
B.B. 49.8 mEq./liter PCO₂ 39.8 mm. Hg.
B.E. +0.05 mEq./liter
The baby remained on assisted respiration for approximately 30 hours and was then placed in an incubator and was allowed to breathe 40% O₂ spontaneously. The baby continued to make satisfactory progress and was discharged from the hospital.
Baby Mc.:
This baby was born at 8:00 A.M. and was not a resuscitative problem. Increased respiration rate and expiratory grunting was noticed by 8:30 A.M. Baby was breathing 40% O₂ and was in an incubator. At 11:45 A.M. blood was drawn from the heel for analysis and O₂ concentration in the incubator raised to 100%.
11:45 A.M. blood gas analysis (Astrup Method):
pH 7.160 S.B. 16.0 mEq./liter
B.B. 39.0 mEq./liter PCO₂ 56.0 mm. Hg.
B.E. -11.4 mEq./liter
3:00 P.M. blood gas analysis (Astrup Method):
Blood drawn from the umbilical artery.
pH 7.18 S.B. 15.3 mEq./liter
B.B. 35.5 mEq./liter PₐCO₂ 45.0 mm. Hg.
B.E. -12.0 mEq./liter PₐO₂ less than 20 mm. Hg.
At 3:00 P.M. the Buck nasal mask was fitted to the infant and cemented in place. The baby's color had been
very poor since 10:00 A.M. The Arp-Varnum respirator was connected to the nasal mask at 3:10 P.M. and operated in the assist mode. 22 cm.\(^3\) of 40% \(O_2\) were delivered each time the baby triggered the respirator. Maximum delivery pressure was 18 cm. H\(_2\)O. Within 2 or 3 minutes the baby quit retracting and grunting. The baby's color was pink at 3:15 P.M. when it went to sleep. The baby remained asleep and calm until blood samples were drawn from the heel at 5:00 P.M.

**Blood gas analysis 5:00 P.M. (Astrup Method):**

<table>
<thead>
<tr>
<th>pH</th>
<th>S.B.</th>
<th>B.B.</th>
<th>B.E.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.30</td>
<td>19.2 mEq./liter</td>
<td>39.3 mEq./liter</td>
<td>-6.0 mEq./liter</td>
</tr>
<tr>
<td></td>
<td>40.9 mm. Hg.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The baby continued to do very well on the respirator and remained pink until 7:00 P.M. At that time the baby gasped several times and expired. The respirator was checked thoroughly and was found to be operating perfectly.

An autopsy was requested to determine the cause of death. The final report gave the cause of death as a massive cerebral hemorrhage. The lungs showed the classic hyaline like membrane.

**Baby Ma.:**

This baby showed signs of respiratory distress immediately after birth with cyanosis, retraction, and expiratory grunting. The baby was placed in an incubator with the \(O_2\) level at 38%. After 1 hour and no great improvement in color the \(O_2\) concentration was raised to 100%. 5 hours after birth a number 5 French catheter was placed in the umbilical artery. A Beckman Model 160 Physiological Gas Analyzer with Modular Cuvettes was used to determine \(pH\), \(P_{aCO_2}\), and \(P_{aO_2}\).

**Blood gas analysis 5 hours after delivery:**

<table>
<thead>
<tr>
<th>pH</th>
<th>(P_{aCO_2})</th>
<th>(P_{aO_2})</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.26</td>
<td>58 mm. Hg.</td>
<td>48 mm. Hg.</td>
</tr>
</tbody>
</table>
A Buck nasal mask was fitted to the infant and cemented in place at this time. The Arp-Varnum respirator was used delivering 27 cm.$^3$ of 90% $O_2$ at a maximum delivery pressure of 22 cm. $H_2O$ each time the infant triggered the respirator.

Blood gas analysis 7 hours after delivery (2 hours on respirator):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7.26</td>
</tr>
<tr>
<td>$P_{aCO_2}$</td>
<td>48 mm. Hg.</td>
</tr>
<tr>
<td>$P_{aO_2}$</td>
<td>120 mm. Hg.</td>
</tr>
</tbody>
</table>

Blood gas analysis 12 hours after birth, 7 hours on the respirator delivering a tidal volume of 30 cm.$^3$ 92% $O_2$ to a maximum delivery pressure of 22 cm. $H_2O$. Baby's color is very good, no retractions or grunting.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7.28</td>
</tr>
<tr>
<td>$P_{aCO_2}$</td>
<td>46 mm. Hg.</td>
</tr>
<tr>
<td>$P_{aO_2}$</td>
<td>110 mm. Hg.</td>
</tr>
</tbody>
</table>

Blood gas analysis 18 hours after birth, 11 hours on the respirator delivering a tidal volume of 30 cm.$^3$ 100% $O_2$ to a maximum delivery pressure of 25 cm. $H_2O$. Baby's color is excellent, no retractions or grunting.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7.33</td>
</tr>
<tr>
<td>$P_{aCO_2}$</td>
<td>44 mm. Hg.</td>
</tr>
<tr>
<td>$P_{aO_2}$</td>
<td>190 mm. Hg.</td>
</tr>
</tbody>
</table>

The nose mask was removed 31 hours after beginning treatment with the respirator to see if the baby could maintain itself while breathing 98% $O_2$ spontaneously. After 1.5 minutes off of the respirator the baby's color had changed from pink to a dusky grey. The mask and respirator was immediately reattached to the infant and assistance resumed.

One would expect the $P_{aO_2}$ to fall when the infant's color changed from pink to dusky grey, however it might be suspected that once back on the respirator the $P_{aO_2}$ would rise rapidly to its former level of 190 mm. Hg. This did not happen. The infant showed very slow improvement in its
color. 7.5 hours after the mask had been removed for only 1.5 minutes a blood gas analysis showed the infant to have a considerably lower $P_{aO_2}$ than is desirable.

Blood gas analysis 45.5 hours after birth, 38.5 hours on the respirator, and 7.5 hours after trial removal of respiratory assistance. 30 cm. $^3$ of 100% $O_2$ had been delivered to a maximum pressure of 25 cm. $H_2O$.

\[
\begin{align*}
\text{pH} & \quad 7.44 \\
P_{aCO_2} & \quad 44 \text{ mm. Hg.} \\
P_{aO_2} & \quad 54 \text{ mm. Hg.}
\end{align*}
\]

This data is a bit frightening in view of the opinion of some researchers, including the author, that there is an unpredictable point-of-no-return in the amount of distress and changes in blood gas values that an infant can tolerate (2). The author believes the amount of stress which can be tolerated and compensated for is continually changing with the progression or regression of the disease. To be absolutely safe in one's decision to try the infant without assistance the author believes that the $P_{aO_2}$ should reach and maintain for several hours a value of 120 to 150 mm. Hg. while the patient is supplied 40% $O_2$ by the respirator. At this point in the progress of the treatment the most critical phase of the disease has been passed and it is only a matter of time before the infant may be safely placed in an incubator containing a 40% $O_2$ atmosphere. This exact time must, as yet, be determined by trial and observation.

The infant's $P_{aO_2}$ finally climbed to 100 mm. Hg. 19.5 hours after the mask had been removed for 1.5 minutes. At this time, 65.5 hours after birth and 58 hours after assisted respiration had been started, the infant's blood gas analysis was:

\[
\begin{align*}
\text{pH} & \quad 7.40 \\
P_{aCO_2} & \quad 45 \text{ mm. Hg.} \\
P_{aO_2} & \quad 100 \text{ mm. Hg.}
\end{align*}
\]
Treatment of this baby continued until the blood $P_{a\,O_2}$ maintained a value of approximately 100 mm. Hg. with the respirator delivering 40% $O_2$. At this time the infant was placed in an incubator with a 40% $O_2$ atmosphere. The baby had been supported by the respirator for 113 hours (just 7 hours short of 5 days).

Gas delivered to the infants had a relative humidity of approximately 50%. This value is considered adequate since the gas passes through the nose which is the body's natural humidifier. 50% relative humidity was obtained by mixing the dry $O_2$ which powers the system with air at 100% relative humidity taken into the system through the auxiliary input. See Figure 9.
DISCUSSION AND SUMMARY

Medical science today is still not certain of the cause of respiratory distress including hyaline membrane disease and does not have a method for the prevention or cure of it. Normalization of pH with administration of intravenous glucose and sodium bicarbonate and other buffering agents has been an aid in controlling the acidosis generally associated with severe respiratory distress (12). This method of treatment, however, attacks only the measurable symptoms or results of the distress. It does little, if anything, to improve the gaseous exchange of the lungs. In other words, normalizing the pH does little to decrease the $P_aCO_2$ or to increase the $P_aO_2$ of the blood or to diminish the amount of work done by the patient in breathing.

Respirators have been used for some time in the treatment of respiratory distress by researchers. However, the use of respirators for treating newborn babies is not common today. There are several reasons why physicians are reluctant to use respirators on newborn babies suffering with respiratory distress. They are: Tracheostomy has been thought by most physicians to be essential for respirator treatment. This, in itself, presents a very serious risk and has a chilling air of finality about it. Most respirators available today are too crude to precisely match the flows and volumes needed by the newborn. Excessive dead space and high resistance precludes the use of many respirators on infants. Flow rates of respirators generally available are too low to meet the infant's demands. In addition, most respirators will not cycle at the high rates which are required for successful treatment and almost all of them fail to trigger reliably on the feeble and very brief inspiratory attempts of the infant. Thomas et al., (11, p. 83) in reference to Benson et al., Heese et al., and Write et al., states that it has
been considered necessary by some researchers to produce complete paralysis to prevent the infant breathing out of phase with the respirator.

The respirator developed during this study requires 0.5 mm. H\textsubscript{2}O negative pressure for consistent and reliable triggering. Triggering level of the respirator is stable even with widely changing compliance of the lungs. The triggering level is usually set at 0.5 mm. H\textsubscript{2}O negative at the beginning of treatment and is not readjusted during the course of treatment. The respirator is usually in operation 2 to 5 days for each patient. The infant develops the 0.5 mm. H\textsubscript{2}O negative pressure to trip the respirator by removing 0.1 cm.\textsuperscript{3} of air from the line at onset of inspiration. Obviously the volume which must be inhaled by the patient before tripping the respirator is just as important as the pressure and is often overlooked as a machine design parameter.

Assisting-flow to the patient begins within 20 ms. after onset of inspiration. This extremely fast start-up time, stability, and sensitivity is unmatched at this time, by any commercially available respirator. The shortest possible start-up time is desirable because the infant cannot be assisted or relieved of any of the work of breathing until the pressures in the thorax and lungs have become positive. Start-up times of 50 ms. and greater as found in most respirators available today allows the infant to be at least one-third finished inhaling before any assistance is given by the machine. In fact, the infant is doing more than normal work until mask pressure attains a positive value.

The positive pressures delivered by a respirator, however, must be precisely timed with the patient's own inspiratory efforts and have a flow characteristic that will relieve the infant of all or most of the work of breath-
ing without interfering with venous return to the heart or diminishing flow and blood volume in the pulmonary vascular bed.

The delivery waveform of the Arp-Varnum respirator has been chosen to give a low mean applied pressure and, therefore, minimizes the disturbance to the circulation of blood through the pulmonary vascular bed. Studies cited by Avery state, "Normal newborn infants may shunt nearly one-fourth of their cardiac output from right to left in the first few days of life. The magnitude of the right-to-left shunt in infants with respiratory distress is much greater, up to two-thirds of the cardiac output (Nelson, 1963) Stang demonstrated a significant negative correlation between alveolar ventilation and right-to-left shunts—the less the ventilation, the greater the shunt (Stang, 1961) (2)."

These large right-to-left shunts help to reduce the pulmonary arterial and systemic arterial pressures to such an extent that the flow of blood through the pulmonary vascular bed is many times insufficient in the cases of respiratory distress to permit a level of gas transfer in the lungs compatible with survival. It should therefore be intuitively obvious that excessive or poorly timed pressures developed by a respirator in an infant's thorax and lungs can further reduce the small flow and volume of blood in the pulmonary vascular bed. The subsequent reduction of gas transfer between lungs and blood can be fatal (9).

Using the Buck nasal mask, respirator treatment of distressed infants can be started very early in the course of the distress without the trauma and usual hazards of tracheostomies or endotracheal tubes. It is believed that the practice of beginning treatment very early may prevent the drastic fall in $P_{a}O_{2}$ which can cause vasoconstriction and reduced blood flow through the pulmonary vascular bed (9), (10). Limited clinical experience tends to support
this belief, however, additional cases are needed to be certain of this contention. $P_aCO_2$ levels can be held between 40 and 50 mm. Hg. without difficulty and pH can usually be maintained between 7.25 and 7.45 if treatment is started before the infant's respiratory rate begins to fall. It is believed that there is an indeterminable point-of-no-return in the worsening condition of the infant where there is too little flow of blood through the pulmonary vascular bed to be able to obtain sufficient gas transfer ($O_2$ and $CO_2$) to sustain life. In regard to this belief, Avery says, "The precise values at which an irreversible stage of hyaline membrane disease has been reached are not yet established...(2)." In view of this, it seems that if there is any doubts at all that the patient will survive the disease, respirator treatment should be started immediately. The Buck nasal mask makes it easy and safe for the infant to be taken off the respirator for periodic assessment of ability to breathe spontaneously and then to quickly continue treatment if necessary.

The respirator described in this study is the basic piece of equipment used in the treatment of respiratory distress. However, the spirometer, tilting bed, and the temperature sensor-controller are considered next to indespensible. It is the attention to small details such as automatic temperature, control, turning of the infant every hour, automatic exposure of radiographs and accurate tidal volume determinations that can make the usually dangerous and technically difficult job of operating a respirator for infants almost routine, yet consistent with usual intensive care procedures.

The system developed for respiratory augmentation of neonates suffering from respiratory distress has been clinically tested. All of the devices appear to be successfully fulfilling their intended purposes.
Further research and clinical use of the respiratory augmentation system is needed to verify with a statistical analysis the degree of increase in survival rate which can be obtained by properly using the system. There is no doubt in the author's mind that survival rate can be increased dramatically. The author is cognizant of the fact that the previous statement is not very scientific. However, one can have no doubts as to the effectiveness of the system when the observer sees an infant's color change from blue to pink, retraction and expiratory grunting stop, and the struggling infant calmly go to sleep 3 to 5 minutes after respiratory assistance is started. The infant awakens, begins retracting and expiratory grunting as soon as the respiratory assistance is stopped. In addition, the infant's color changes within a minute or two from pink to purple. The author firmly believes that this system for treating respiratory distress is a major advance in technology and technique that can save many of the 25,000 newborns who now die needlessly.
CITATION OF LITERATURE


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