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An Inspiration-triggered Delivery System for Oxygen Therapy via a Nasal Cannula

Philip Charles Krause

Charles F. Babbs
Purdue University, babbs@purdue.edu

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PHILIP CHARLES KRAUSE, CHE, AND CHARLES F. BABBS, MD, PHD

Biomedical Engineering Center, Purdue University, West Lafayette, Indiana, USA.

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ABSTRACT

Therapy for severe chronic lung disease currently includes the administration of supplemental oxygen to prevent breathlessness and tissue hypoxia. Although effective, this therapy is unnecessarily costly, because oxygen is administered to the patient during expiration as well as inspiration. To eliminate this inefficiency, a delivery system that senses the inspiratory effort and delivers oxygen to the patient only during inspiration was developed. The 11 × 5 × 8-cm flow control unit attaches easily to a portable oxygen supply. The components of the system have an expected life of five years, and the 9-Volt battery provides power for about one month of use. Manual controls permit accommodation to the respiratory pattern of the patient. Preliminary evaluation of the system showed that its effectiveness in producing tissue oxygenation is similar to that of continuous oxygen systems. The system has potential applications in ambulatory oxygen therapy and in other clinical settings to improve the cost/benefit ratio of oxygen treatment.

Key words: ambulatory oxygen, chronic obstructive pulmonary disease, COPD, heath care cost, reduce, reduction

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INTRODUCTION

Ambulatory oxygen therapy is becoming an increasingly accepted part of the regimen for the management of patients with chronic obstructive pulmonary disease (COPD). In 1976 Levine et al.[1] documented overall clinical improvement in patients with COPD who were receiving continuous low-flow oxygen therapy during daily activities. In their study, patient comfort was greatly improved by the development of a nasal cannula made of unobtrusive, soft plastic. After a month of continuous oxygen delivered by nasal cannula, five of the six patients were able to participate in a rehabilitation program, and the management of respiratory and cardiac problems was simpler. The authors stated that "long-term continuous O_2 therapy caused significant clinical improvement in every patient."

Two recent reports, one from Great Britain and the other from the United States, have confirmed the benefits of long-term oxygen therapy. In the American study [2] results in patients with COPD, randomly assigned to continuous oxygen therapy (19 hours/day) were compared with those in patients receiving oxygen therapy only nocturnally (12 hours/day). The results showed the mortality of the nocturnal oxygen group to be almost twice (1.95 times) that of the continuous oxygen group. The British study [3] compared 15-hour nocturnal oxygen treatment with a treatment regimen that did not involve supplemental oxygen, administered to a control group. During a five-year period the mortality in the oxygen group (12 per cent/year) was less than half that of the control group (29 per cent/ year). Based on this and other research, oxygen administration has become an accepted part of the therapy for chronic lung disease. The results to be expected are 1) increased exercise tolerance, 2) reversal of hypoxia-induced pulmonary hypertension, 3) reduction in hypoxia-induced polycythemia, and 4) improved mental status [4].

Long-term continuous oxygen therapy for ambulatory patients became practical in 1967, with the introduction of a portable system that used liquid oxygen [5]. The light-weight apparatus contained a four-hour supply of oxygen when set at a flow rate of 2 L/minute. A reservoir tank of liquid oxygen installed in the patient's home allowed refilling of the portable system. The effectiveness of a liquid oxygen source was proved by Petty and Finigan [6], who showed that liquid oxygen systems are as effective as compressed oxygen sources. Alternatively, an oxygen concentrator may be used in the home [7]. This machine uses a molecular sieve to separate room air into oxygen and nitrogen, collecting the oxygen and delivering it to the patient. Continuous oxygen treatment from the oxygen concentrator is five to seven times less costly than the same treatment from an oxygen cylinder. The currently used oxygen administration systems for chronic therapy, incorporating either liquid oxygen or an oxygen concentrator, still have drawbacks. The liquid oxygen apparatus is expensive, as is the refilling of the home reservoir. In addition, the 3.8-kg portable system is too heavy for patients with advanced stages of COPD. The oxygen concentrator requires a large initial investment and tethers the ambulatory patient.

An inherent inefficiency of most systems currently used is that a continuous flow of oxygen is delivered to the patient, although that delivered during expiration is obviously wasted. An automatic system that delivers oxygen only during inspiration could, in principle, improve the efficiency of current oxygen systems by reducing both operating costs and the size and weight of the necessary apparatus. This paper describes a novel system designed for that purpose.

INSPIRATION-TRIGGERED DELIVERY SYSTEM

Figure l is a block diagram of the demand delivery system. The system incorporates a high-sensitivity pressure sensor in line with a conventional nasal cannula to monitor the pressure fluctuations in the nares inherent to respiration. Sharp negative going pressure waves at the onset of inspiration serve as a trigger signal, initiating gas flow for a preselected time-out period. In particular, when the absolute value of this negative pressure signal exceeds a threshold value, the control electronics activate the valve to send a pulse of oxygen to the patient.

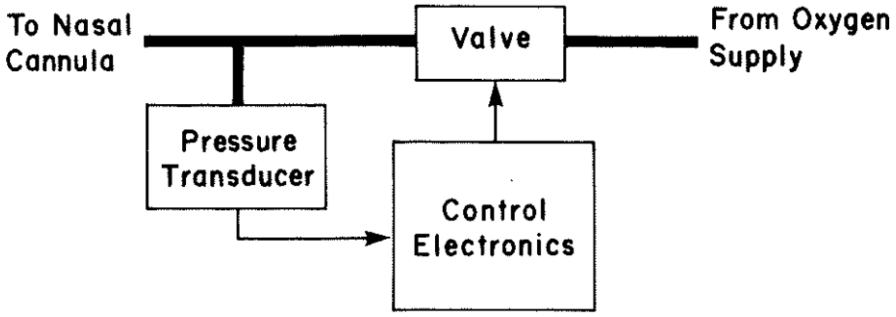

Figure 1. Component configuration for the demonstrator prototype.

Figure 2 illustrates the pressure signal recorded with such a transducer through a nasal cannula during normal quiet breathing in a healthy volunteer. In this record, made with a sensitive Statham #P23BB venous blood pressure transducer, a downward deflection represents negative pressure, or inspiration, and an upward deflection represents positive pressure, or expiration. The calibration shows that the signal amplitude is in the range of 0.5 to l.0 mmHg, similar to that reported earlier by Guyatt and associates [8]. The inspiratory phase, which begins with a sharp negative deflection, constitutes less than half of the respiratory cycle. The pathologic features of COPD, i.e., the loss of elastic recoil and airway collapse, would cause exaggeration of the length of expiration but would not be expected to change the shape of the inspiratory portion of the cycle greatly. Accordingly, we selected the negative deflection in pressure at the beginning of inspiration to trigger the flow of oxygen in our system.

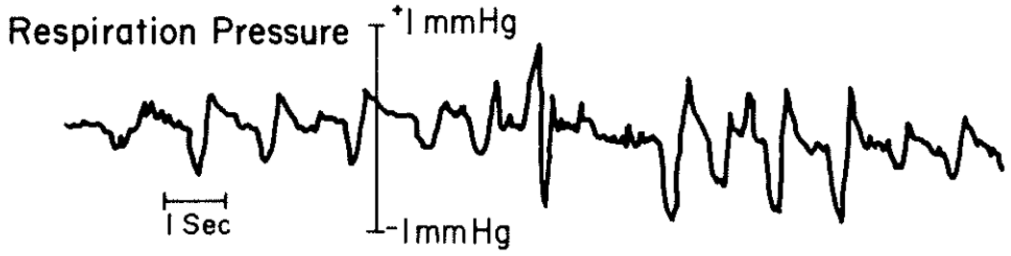

Figure 2. Initial measurement of nasal breathing with a nasal cannula used as a pressure-sensing tube. In this record an upward deflection represents positive pressure, or expiration.

Our first prototype was equipped with two control knobs, allowing the patient to adjust manually both the trigger threshold level and the duration of the delivered oxygen pulse. The adjustable duration feature permitted two qualitatively different modes of operation of the system (fig. 3).

In what we have called the manual mode, the user selects a gas pulse duration, in the range of 1 to 2 seconds, that is roughly the same as the duration of inspiratory effort. With each inspiration the user receives a single pulse of gas. If the duration of inspiration changes, as in exercise, the user can manually adjust the duration of the gas pulse.

In what we have called the automatic mode, the user sets the duration in the range of 0.1 to 0.2 seconds, which is significantly less than the duration of normal inspiration. This system delivers a brief pulse of gas, terminates flow, and then continues sensing. If inspiration continues, negative pressure is quickly registered and another pulse of gas is delivered. The overall effect is to produce a train of gas pulses that is nearly coincident in overall duration with the inspiratory effort. Thus, the automatic mode adjusts to changes in the duration of inspiratory effort, and flow is interrupted briefly during inspiration to permit sensing.

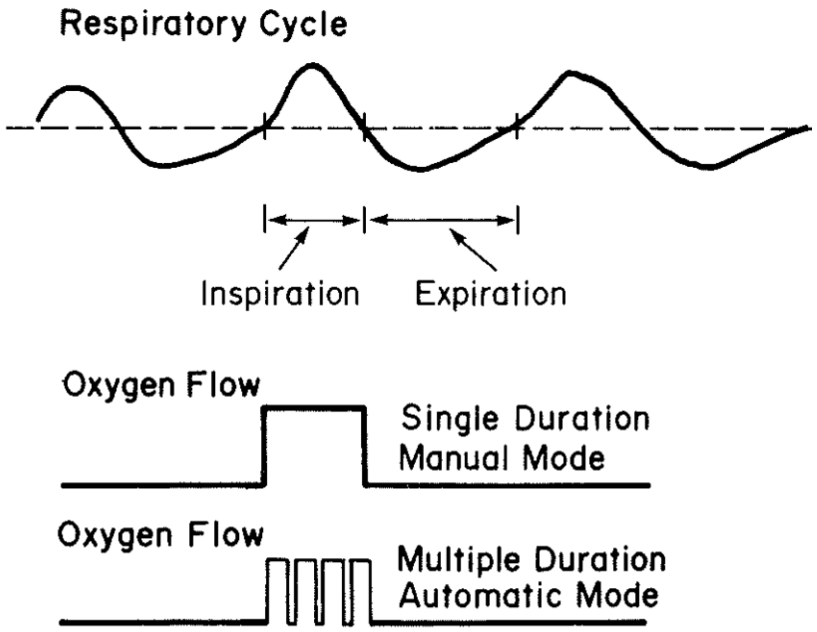

Figure 3. The concept of the demand delivery system involves delivery of a pulse of oxygen during inspiration. By adjusting the pulse duration, two operating modes were developed.

Performance Records

Figures 4 and 5 illustrate the performance of the demand delivery system in both the manual and automatic modes of operation. In these graphic records, the top channel illustrates pressure within the nasal cannula in the form of the transducer output signal. The second channel illustrates the state of the control valve, either open or closed, and the third channel illustrates gas flow through the nasal cannula as measured with a pneumotachograph. In the manual mode (fig. 4) the record illustrates that a slight negative pressure sensed by the transducer (an upward deflection represents negative pressure) causes the valve to open and gas to be delivered for the preset pulse duration of 1 second. In this three-breath record, the length of inspiratory effort is constant, representing the most efficient situation for the manual mode of operation.

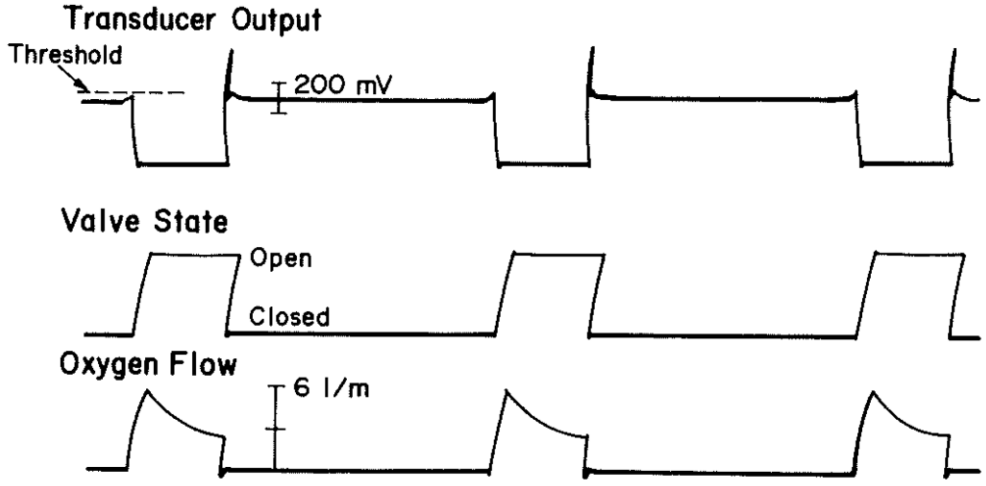

Figure 4. Performance record of the demonstrator prototype in the manual mode of operation. The exponential decay in oxygen flow is caused by discharge of the pneumatic capacitance between the demand value and the flow control valve. Tilt of waveforms is caused by the arcs of direct writing pens.

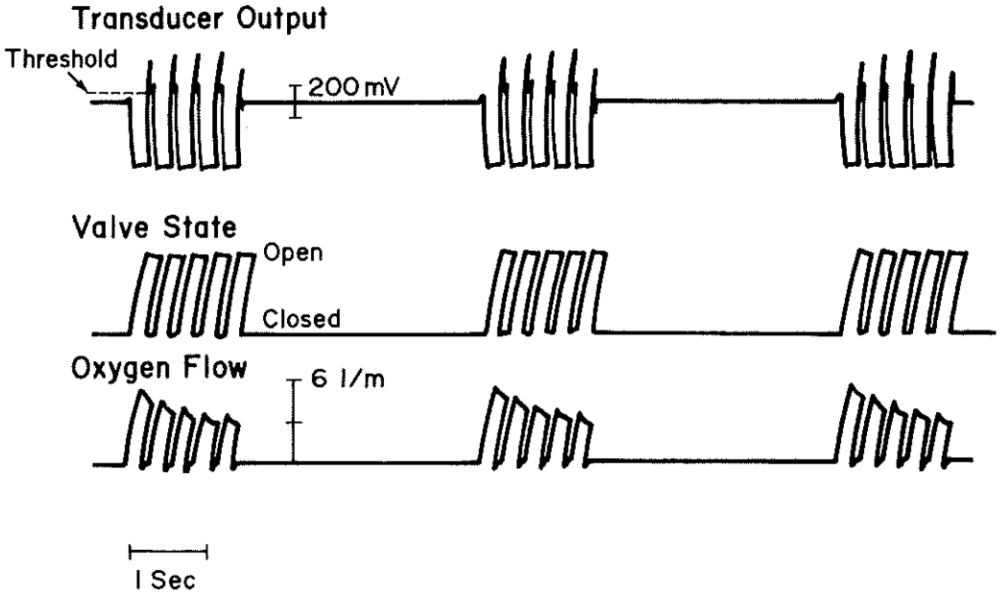

Figure 5. Performance record of the demonstrator prototype in the automatic mode of operation.

Figure 6. Various forms of noise that could occur during respiration and a record of their effect on the system pressure transducer.

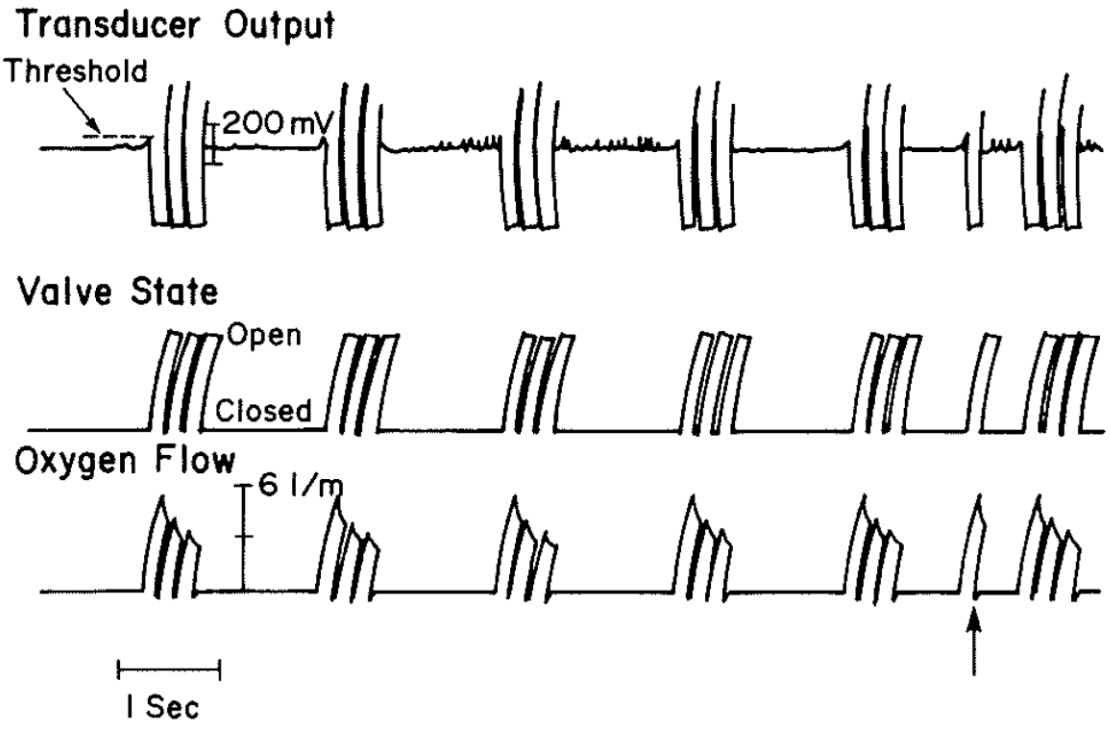

Figure 7. Performance record of the demonstrator prototype in the automatic mode of operation. Noise was introduced by shaking the oxygen tubing, and a single ill-timed pulse of gas (arrow) was delivered when the system interpreted the noise as an inspiratory effort. Tilt of waveforms is caused by the arcs of direct writing pens.

In the automatic mode (fig. 5) the pulse of shorter duration allows the transducer to sense for inspiration more frequently. While the transducer is sensing, no gas is flowing to the patient. This interruption in flow, or off-time, is inherent in the automatic mode and can be compensated for by increasing the flow setting slightly to achieve a desired mean flow rate. It is easy to see how, with this mode, the system can automatically adjust to changes in the duration of inspiratory effort.

Response to Noise

In a further performance test we investigated the function of the system when challenged by various forms of noise. We observed that speaking, talking, and shouting all generated positive pressure at the transducer and did not activate the flow control valve (fig. 6). Noise due to shaking and crimping the short tube that connects the outlet barb of the oxygen supply to the inlet port of the unit can introduce occasional spurious pulses of flow (fig. 7, arrows). Should the unit fail; the user can quickly bypass the control valve by directly connecting nasal cannula tubing to the oxygen supply, as it is normally done for continuous oxygen delivery.

The portable prototype (fig. 8) included a sensitive pressure transducer (Microswitch, Series 160) and a bistable electronic latching valve (Reedex). Both were powered by a common 9-Volt transistor radio battery that was also contained within the Unibox. The estimated life of the battery is one month of heavy use. The sensitivity knob on the top of the unit controlled the trigger threshold, corresponding to the strength of inspiration required to cause the electronic system to open the valve. The duration knob controlled the duration of the pulse of oxygen flow. As an aid to adjustment of sensitivity, we incorporated a light-emitting diode (LED) into the circuitry that would flash coincident with the valve opening. The LED was placed next to the control knobs, allowing the user to monitor its display, while adjusting the sensitivity control knob. When the light flashed with every breath, the sensitivity was properly adjusted.

Another added feature was a test position on the power switch. This switch position allowed the user to activate the demand valve manually to ensure that it was working properly. We had noticed in developing the system that it was difficult to detect the flow of gas through properly positioned nasal prongs, when flow occurred strictly during inspiration. In his sense, treatment by demand delivery of oxygen is much more comfortable than treatment with continuous oxygen--so much so that it is difficult to notice the gas flow. Using the test switch with the unit turned on and connected to the oxygen supply, the user could test the system by placing the nasal cannula close to the cheek and noticing a puff of gas. Such a test would reassure the user that the system was assembled and functioning properly.

Preliminary Evaluation

As an initial test of the effectiveness of our unit, we performed the following evaluation on a normal healthy subject. Transcutaneous PO_2 was measured on the subject's forearm, as an indicator of systemic tissue oxygen tension, with a Novametrics Model 809 $TcPO_2$ sensor. The

subject was careful to maintain a constant breathing pattern, as changes in depth and rate of respiration will affect the $TcPO_2$ measurements. Figure 9 illustrates the results of the study, showing that an intermittent flow system can produce therapeutic increases in tissue oxygen tension, similar to those produced by continuous oxygen delivery in a normal subject.

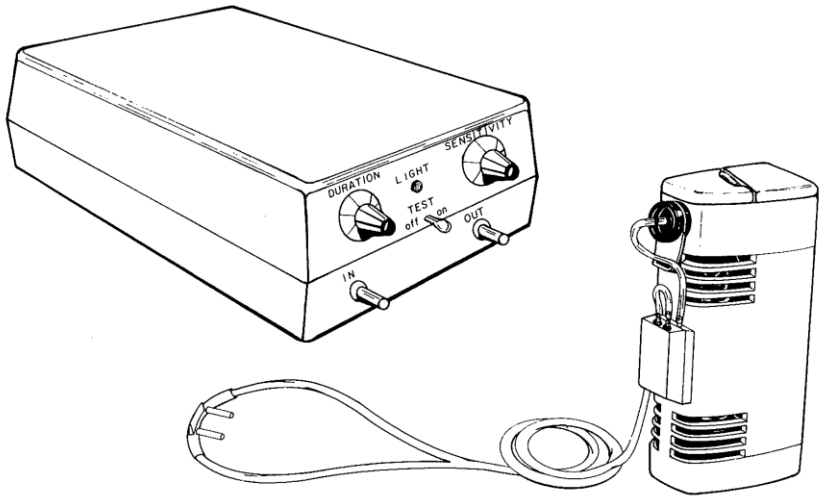

Figure 8. Left, inspiration-triggered delivery system in its packaged form. Right, portable demand delivery system attached to a Stroller II portable liquid oxygen supply.

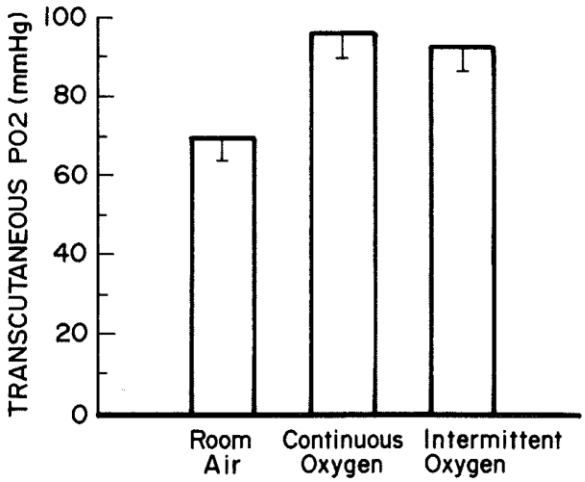

Figure 9. Transcutaneous oxygen pressure as measured on the forearm of a single subject, breathing room air, continuous oxygen, or intermittent oxygen. Each bar represents the mean of eight to ten separate trials, including room air breathing and oxygen supplementation. The error bars denote standard deviations.

DISCUSSION

The system described is by no means the first to permit oxygen delivery in phase with inspiration. In 1962 the Palm Breathing Device [9] was developed for intermittent oxygen therapy. During inspiration, the patient induced a flow of oxygen by depressing the control button with the thumb; flow was arrested when the button was released. The system was inexpensive and simple, but the manual control made it highly impractical for other than short-term use by well-motivated patients. In 1972 the first portable automatic delivery system was developed for ambulatory patients [10]. In this system, referred to as the Automatic Belt Breathing Device, the flow of oxygen was activated by a switch contained in a special belt worn by the patient. Triggered by expansion of the chest or abdomen, the system proved effective but was not widely accepted because the belt was uncomfortable and subject to false flow triggers with changes in body position. The designers of these systems realized the potential savings of a demand oxygen system; however, they lacked the technology to implement such a system successfully. Our goal was to design and build an inspiration-triggered oxygen delivery system that would be practical, unobtrusive, and efficient and that would not require extensive patient cooperation.

The inspiration-triggered delivery system described in this paper includes an electrically controlled valve that delivers therapeutic oxygen to the patient coincident with inspiration. Modern electronic technology allowed packaging of the entire system in a small, light-weight plastic box (approximate dimensions, $11 \times 8 \times 5$ cm; weight, 130 g). The components are durable and should last approximately five years (excluding the battery). A 9-Volt transistor radio battery powers the system and provides energy for about one month of heavy use. To ensure patient comfort and compatibility, the system can be adjusted to match the patient's respiratory effort and length of inspiration. Preliminary laboratory testing showed that the system is as effective as continuously delivered oxygen in elevating tissue oxygen concentration.

Because it delivers oxygen only during inspiration, the device could reduce the cost of oxygen therapy, reduce the size of the necessary apparatus, or both. Although designed to facilitate portable liquid oxygen delivery; the system has applications in other areas. For example, the unit could be used with conventional oxygen outlets in hospitals to reduce the cost of inpatient oxygen therapy. Its effective operation and wide range of applications would seem to ensure a promising future for the system.

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