A novel physiologic sampling pump capable of rapid response to breathing†‡

Larry Lee,*[a] Michael Flemmer,[a] Eun Gyung Lee,[a] Martin Harper,[a] Ming-I Lin,[b] William Groves,[b] Andris Freivalds[b] and James Slaven[a]

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The merits of using physiologic sampling pumps (PSPs) instead of using constant-flow sampling pumps, *i.e.*, "traditional sampling pumps" (TSPs), are discussed. A novel PSP that overcomes shortcomings of previous PSP designs is presented. Calibrated valves are used to obviate pump inertia that has limited the system response and accuracy of prior work. Technologies that provide minute ventilation ($\dot{V}_E$) of subjects in real time may therefore be used to the limit of their own accuracies to sample inhalation exposures. Analysis of the design and data from a prototype are presented to show how air sampling can be modulated to follow breathing.

Introduction

Assessing worker exposures to airborne hazards is an essential element of industrial hygiene practice. Personal exposures must be known in order to (1) determine compliance with exposure limits set by various regulatory agencies, (2) specify personal protective equipment to be worn to isolate workers from hazards, (3) tailor the design of control systems for work sites and to measure the effectiveness of these controls, (4) develop databases for epidemiological dose-response studies, and (5) project the risks of contracting diseases from exposures. Collecting samples representative of exposures is the foundation underlying valid assessment.

Traditional sampling pumps (TSPs) are the standard tools used to collect the samples. These pumps have become more convenient to use, as electronic parts have become smaller and the energy density of batteries has increased. They have also become more accurate, precise, and reliable as manufacturers have leveraged advances in technology. TSPs, however, only help determine the time-weighted average concentration of contaminants in the ambient air (mg m^{-3}), which is calculated by dividing the mass of the contaminants collected (mg) by the product of sampling duration (min) times the constant flow of the pump (m^3 min^{-1}, more commonly expressed in cm^3 min^{-1}, or L min^{-1}). TSPs cannot account for variations in a user's inhalation since they sample the air continuously at a constant flow which is preset by the user or industrial hygienist. Since pulmonary ventilation during strenuous work may be up to ten times of that while resting,[1] concentration may not correlate well with the actual mass inhaled.

Moreover, exposure concentration may be strongly correlated with exertion. Kucharski's[2] field study found a statistically insignificant relationship between the mass of dust collected on a reference respirator filter and that collected by his implementation of a physiologic sampling pump (PSP), the personal dust sampler (PDS), whereas a significant difference in mass was collected by a TSP. Kucharski[2] noted, however, that the problem of size selective sampling when using the PDS had not been resolved. Satoh *et al.*[1] and Levine[3] did not report using their instruments to test this relationship. Hart's[4] data revealed no significant correlation, but indicated that size and protocol limitations of the field study prevented her from drawing any conclusion. Further research with better methods and instrumentation is required to draw valid conclusions.

Prior work

All prior work except Satoh *et al.*[1] are TSPs modified to function as PSPs. The modified units calculate estimates of a subject's minute ventilation ($\dot{V}_E$) and then vary the speed of the pump accordingly so that the volume of air being sampled is proportional to the subject's inhalation. Levine[3] used thoracic impedance to estimate $\dot{V}_E$. Kucharski[2] used heart rate (HR) to calculate these estimates for his PDS, as did Hart[4] who coined the nomenclatures "physiologic sampling pump" and "physiologic volume-weighted average." Satoh *et al.*[1] had subjects exercise while wearing HR, temperature, accelerometer, and other environmental sensors connected to a data logger, but their approach was inherently limited to direct reading sensors. From their regression equation, they found that HR could estimate pulmonary ventilation with less than 30% error, but no further evaluation of their method has appeared in the literature. Hart's 291 page dissertation[4] is the only publication about PSPs that presents and analyzes extensive data. Any discussion of prior art is essentially a consideration of her work.

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[a] *National Institute for Occupational Safety and Health (NIOSH), Health Effects Laboratory Division (HELD), Morgantown, WV, 26505-2888, USA*
[b] *The Pennsylvania State University, University Park, PA, 16802-5000, USA*

† Information related to the technology including licensing opportunities may be obtained by writing to Kathleen Goedel, Technology Development Coordinator, Office of Research and Technology Transfer, NIOSH, Centers for Disease Control and Prevention (CDC), 4676 Columbia Parkway, MS C-09, Cincinnati, OH 45226, USA. E-mail: kgoedel@cdc.gov, Fax: +1 (513) 533-8660, Tel: +1 (513) 533-8686.

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There is an inherent performance trade-off in these PSP designs. Levine[3] expressed the problem when he stated that "Due to the mechanical limits of pump response speed, the differential values were averaged over 15 second periods and scaled before being outputted. The 15 second averaging period was long enough to allow a resting wearer several complete breaths." Yet, data from Lee *et al.*[5] found that the magnitude of exposure concentration indoors may change an average of 15% within 4 s with a standard deviation (SD) of 20% ($n = 284$) even when source concentration was held constant. Hart[4] performed rigorous experiments and determined that the pumps she used stabilized to new speeds in about 1 s (page 128). Hart[4] (page 68) expounded upon the trade-off well when she reported that "One notable PSP design issue is the balance between the averaging time for the input signals and the update period for the output voltage to the pump. The shorter the averaging period, the better the PSP will be able to capture peak exposures; unfortunately, this must be balanced against the error introduced by 'wind-up time'. This particular error [wind-up time] is inherent in a mechanical pump that changes flow rate because of inertia in the mechanical system; there must be a transient period during which the pump rate approaches the steady-state pump rate for a given input voltage. To minimize this error the update period between changes in flow rate should be much longer than the time constant for the pump to reach a new equilibrium condition. The more frequently the pump rate is altered, the more error will accumulate. A 15-second averaging period for the input signal was selected for two reasons: (1) it would be long enough to limit the error associated with the pump response transients just mentioned, and (2) research performed by Mermier *et al.*[6] concluded that 15-second averages of heart rate were closely linked to minute ventilation."

Hart[4] presented an extensive variety of statistics for her PSP, but no statistical method was used to delineate the sampling error caused just by the pump motor. Some of these statistics from each run delineated the total volume commanded of the pump motor (Table 12, ref. 4) *vs.* the total volume measured (Table 14, ref. 4), and were graphically presented in Figure 42 (ref. 4) as "PSCU Total Inhaled Volume Estimates *vs.* Mass Flowmeter Total Inhaled Volume Estimates." Figure 42 (ref. 4) reported an $R = 0.97$, but no averages nor *SD*s to delimit total input-output error just for the pump motor.

To better determine the performance of Hart's PSP, we entered Hart's data from Tables 12 and 14 (ref. 4) into a spreadsheet. After eliminating incomplete entries, the spreadsheet processed data from 118 runs. The spreadsheet calculated that total volume as measured by the mass flow meter differed from the total volume commanded of the pump motor by an average of −1.4%, but the average difference of the absolute values was 6.2%, and the SD was 7.5%. These errors were experienced for the 15 s update periods of the pump speed, but would multiply if the update period was divided in an attempt to reduce the error contributed by estimating $\dot{V}_E$ from the 15 s averages of HR. Hart did not provide data to allow calculation of instantaneous flow error attributable to the pump motor response.

Hart's[4] confidence in estimating $\dot{V}_E$ from 15 s averages of HR should be further examined. Mermier *et al.*[6] say that their data *suggests* that 15 s averages of HR are tightly coupled to $\dot{V}_E$, but then emphasize several limitations with the data. First, they found it necessary to develop regression equations tailored for each individual subject, otherwise substantial variability was observed. Substantial interindividual variability was documented even within strata defined by sex and age. Four unique sets of coefficients were used per subject over a range of HRs. Moreover, they suggested that further research include test protocols more relevant for typical activity. These limitations discussed by Mermier *et al.*[6] imply that if a general equation for estimating $\dot{V}_E$ uses 15 s averages of HR, then other physiologic parameter(s) with optimized weighting(s) should refine the solution.

Hart[4] did in fact augment HR with other parameters, but she nevertheless found that overall performance fell short of her precision goals. The Direct HR Method used individually optimized calibration curves and only HR; the other parameters used for the Indirect HR Method included resting HR and weight; and for Satoh's[1] HR Method, resting HR, height, weight, and age. The total inhaled volume calculated by the Direct HR Method, Indirect HR Method, and Satoh's HR Method, deviated from the primary standard (pneumotachometer) with means of 13%, 21%, and −33%, and *SD*s of 18%, 21%, and 15%, respectively, each with $n = 30$.

The amount of error introduced by 15 s averaging will vary, and depends upon numerous factors, one being the exercise protocol, another the physical fitness of the subject,[6] and as mentioned, how quickly the exposure concentration changes. Worst case analysis would be experienced when a subject begins from rest and rapidly increases workload, and when going from a heavy workload to rest. Again, data varies considerably, but HR recovery rates have been recorded showing drops as much as 40 beats per min (BPM) over the first min after exercise.[7]

Instantaneous methods for measuring $\dot{V}_E$, such as a respirator fitted with a pneumotachometer (PT), are useful for laboratory studies, but are cumbersome for a subject to wear while working, and may also alter inhalation.[8–10] Because developing better ways to determine $\dot{V}_E$ in the field is, itself, a formidable undertaking, the scope of the current effort was limited to building an accurate and precise PSP that may be programmed to work with various predictive equations. To exercise the PSP, an equation using rolling 30 s averages of HR augmented with other data was used to estimate $\dot{V}_E$.[11] Sampling was updated once per second based upon these estimates, but the flow through the pump motor was held constant. Since adults performing heavy exercise rarely exceed more than 60 breaths min^{-1},[12] using a design that updates sampling once each second was chosen to accommodate any potential alternative methods for obtaining $\dot{V}_E$ for field use.

PSP design

The NIOSH PSP is a new design with several custom features, not a modified TSP, although it may be operated in either PSP or TSP mode. The PSP uses a diaphragm pump to move air at rates up to 200 $\text{cm}^3\ \text{min}^{-1}$ at standard temperature and pressure (STP). An air cavity filters pulsations produced by the pump. Non-volatile memory can store data from dozens of sampling sessions. All data records are date and time stamped. Data for TSP and PSP modes include cumulative sampling time, cumulative volume sampled, status (idle, run), fault and error conditions, ambient temperature (°C), atmospheric pressure (in water), battery voltage, and for PSP mode, scaling factor, HR and resting HR in BPM, gender, age in years, height in inches, and weight in pounds. All menu items are accessed and selections made using the two buttons below the liquid crystal display (LCD). Each button has both "tap" and "hold" functions that operate in a fashion similar to numerous other electronic products. A serial port on the bottom of the case accommodates a standard DB-9 connector. Data may be downloaded through this port to a computer for analysis. The PSP is powered by a Sony, Corp. (Tokyo, Japan) NP-QM51H or NP-FM90 or equivalent lithium ion camcorder battery that can power the PSP for up to 2½ or 10 hours, respectively. It may be easily removed for charging on a Sony Corp. (Tokyo, Japan) model AC-SQ950D desktop charger. A belt clip on the back allows the user to conveniently carry the pump. An air tube runs from the pump to the sampling head that is clipped onto clothing in the subject's breathing zone. The PSP is shown in Fig. 1.

A LifeShirt® System (VivoMetrics® Inc., Ventura, CA, USA) is currently being used to provide data for the PSP to calculate the $\dot{V}_E$ of the user, although the PSP may be reprogrammed to process signals from other sensors. The user wears this LifeShirt® System that consists of a lightweight, vest-like garment that is connected *via* a cable to a small personal data assistant which VivoMetrics® Inc. calls a recorder. Electrocardiogram (ECG) electrodes sense HR. A three axis accelerometer senses activity. The recorder receives the sensor signals, processes, logs, and passes the data records to the PSP each second. The PSP receives these data records through a second serial port connector that is located on the bottom of the case. $\dot{V}_E$ is currently being calculated using an equation derived from the collateral work of Lin *et al.*[11] who evaluated the LifeShirt® System for use in upcoming PSP field tests. The parameters used in their equation are the user's HR and motion index (both from the LifeShirt®), age, gender, height, weight, and resting HR. The motion index is a measure of activity which is based on the accelerator outputs and has a range of 0–255. The algorithm is proprietary. The calculated $\dot{V}_E$ is then used to control the air flow while sampling.

Fig. 1 The NIOSH PSP.

The pump motor is constrained to run at a constant flow since varying its speed would limit system response time. Fig. 2 shows a block diagram of the feedback loop that controls the speed of the pump. A proportional-integral-differential (PID) feedback control loop maintains this constant flow. Systematic tuning of the coefficients in the PID algorithm when the program code was being written insures stability and provides the necessary capture and lock ranges to acquire the air flow set point. The air flow is monitored using a AWM3100V mass air flow (MAF) sensor (Honeywell, Inc., Freeport, IL, USA) that has a 1 ms response time. The output from the MAF sensor goes to a low pass filter (LPF), is subtracted from the set point voltage in a differential error amplifier, and then the error voltage is sent to a microcontroller (μC) from an analog to digital converter (ADC). Next, the PID algorithm that runs in the μC uses this error signal to calculate the new voltage to send to a digital to analog converter (DAC). The analog output from this DAC controls the voltage of a power supply that is connected to the pump. Once the new voltage is applied to the pump, the air flow adjusts to correct any deviation from the set point. The PID algorithm executes in 5 ms, but since corrections are made ten times each second the μC spends 5% of its time controlling the pump speed.

The PSP responds to both slow and abrupt changes in loading. Buildup on the collection medium might increase resistance to air flow. This increased loading is counterbalanced by the PID feedback control loop increasing the speed of the pump to maintain the constant flow. Buildup is gradual compared to the response time of the pump and therefore does not affect system stability. On the other hand, an abrupt change in air flow might occasionally occur if, for example, clothing would inadvertently cover the air inlet. The PID will sense this blockage and if the condition lasts for 5 s the program will stop the pump. The program then waits another 5 s and restarts the pump. If the blockage persists, a fault condition is declared and the sampling session is ended.

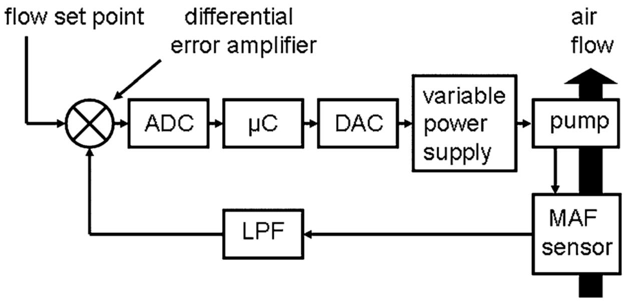

Fig. 2 Block diagram of the feedback loop that controls the speed of the pump. The μC runs a PID algorithm that keeps a 200 $\text{cm}^3\ \text{min}^{-1}$ air flow at STP for PSP mode. The set point may be changed to provide a different flow when used in TSP mode.

A valve placed between the sampling medium and the pump is the key to fast response. Flow is routed through the sampling medium for the fraction of each second necessary to make sampling volume proportional to $\dot{V}_E$, as estimated by the rolling averages. The equivalent of a variable flow is thereby produced through the PSP sampling medium that will be referred to as the effective flow. The valve diverts air flow through the TSP mode path for the remainder of each second. PSP mode sampling and inhalation are now both intermittent, giving the NIOSH PSP the flexibility to respond to $\dot{V}_E$ inputs on a breath by breath basis, if real time $\dot{V}_E$ measurements become practical.

The system response time is dominated by the LPF formed by the sampling medium and air tube, not by the valve. Air flow is controlled by a LHDA0531115H three-way valve (Lee Company, Essex, CT, USA) that has a typical response time of about 3 ms. Oscilloscope displays of the output of an AWM3100V MAF sensor shown in Fig. 3 indicate that when the sampling medium and tube are connected to the valve the overall response time increases by more than an order of magnitude and the air flow is skewed.

Although theoretically corrections might compensate for the skew, the calibration would be complex. When the valve is actuated for a small portion of the 1 s interval, all of the air flow is confined to the same interval (see Fig. 3A). As the actuation time increases, a threshold is reached when the air flow cannot return to zero without continuing into the next 1 s interval (see Fig. 3B). If the valve actuates again at the beginning of the next interval, the total volume sampled will be less than logged. Volume residuals would need to be calculated and tracked in order to correct this error. Moreover, if the pump is used in a dusty environment the sampling medium might experience buildup causing increased resistance to flow. As detailed above, the pump counterbalances increased resistance to maintain constant flow, but the increase, nevertheless, reshapes the envelope of the flow and compounds the complexity of flow corrections by requiring dynamic calibration during sampling sessions. A simpler and more reliable solution was developed.

Changing the configuration accommodates a rapid system response. At the instant the valve is actuated, the pump begins evacuating air molecules from the tube which causes a pressure drop across the sampling medium resulting in flow. Eventually the flow through the sampling medium rises to the constant flow of the pump and the system reaches the steady state. The time required to rise from 10% to 90% of this constant flow is called the rise time. After the steady state is reached flow remains constant until the valve is de-energized. When the valve is de-energized, the air tube is still partially evacuated and the pressure drop continues to cause air to flow through the sampling medium into the tube. As air continues flowing into the tube the pressure drop diminishes until the flow stops. The time required to go from 90% to 10% of the constant flow is called the fall time, and like the rise time, the associated time constant is determined by the physical characteristics of the sampling medium and the air tube. If the air tube is made shorter and shorter until its length approaches zero, then the amount of air inside the tube approaches zero, the time to evacuate the air approaches zero, and the rise and fall times of the system approach zero. Although it is not practical, nor desirable to eliminate the air tube, moving the valve from inside the PSP case to immediately downstream from the sampling medium provides an equivalent effect (see Fig. 4A). The expanded time base used for Fig. 4B shows a transition of about 10 ms, which translates to a system response approximately 100 times faster than prior art.

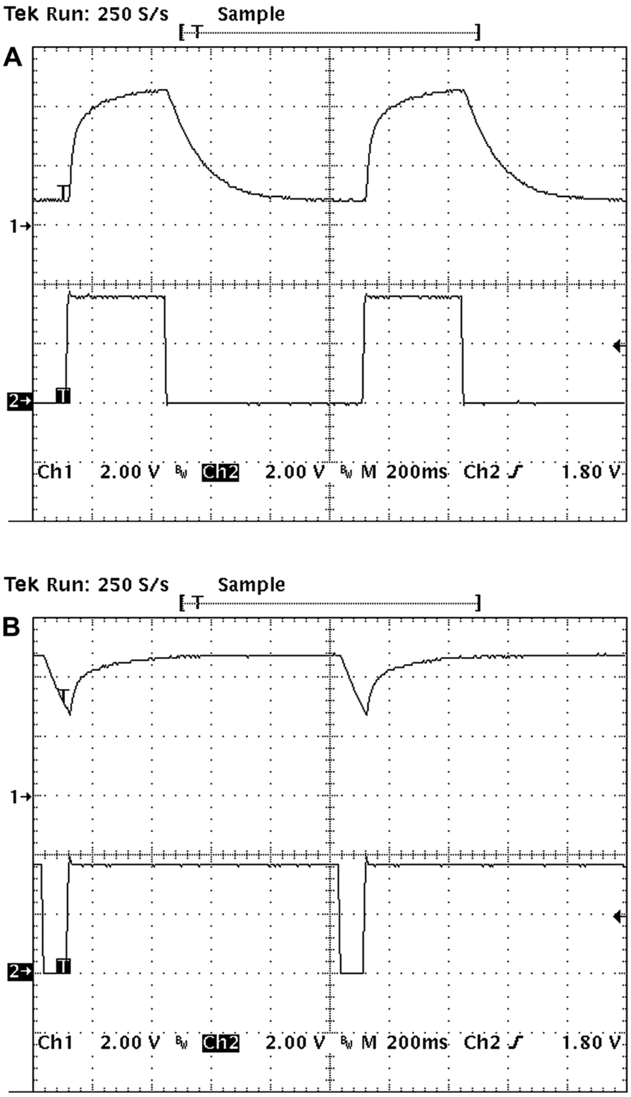

Fig. 3 Air flow at the inlet of a charcoal tube (top traces) is skewed when the flow control valve is mounted inside the PSP case. The valve control signal (rectangular traces) is normally actuated each second. (A) Flow returns to zero for shorter actuation times, (B) flow encroaches into the next interval for longer actuation times. The oscilloscope was set for 200 ms per horizontal division.

A custom sampling head houses the charcoal tubes, the valve, and associated parts. The charcoal tubes, SKC, Inc. (Eighty Four, PA, USA) part 226-01, each consist of two sections (100 mg and 50 mg screened between 20 mesh, 0.84 mm, and 40 mesh, 0.42 mm) with foam and glass wool separators and a proprietary coconut shell charcoal sorbent housed in a 6 mm diameter by 70 mm long glass tube. One charcoal tube collects the sample, the other one presents an equivalent resistance to flow during the portion of each second that flow is diverted away from the sampling medium by the valve. In TSP mode air will flow continuously through the TSP sampling medium with the valve

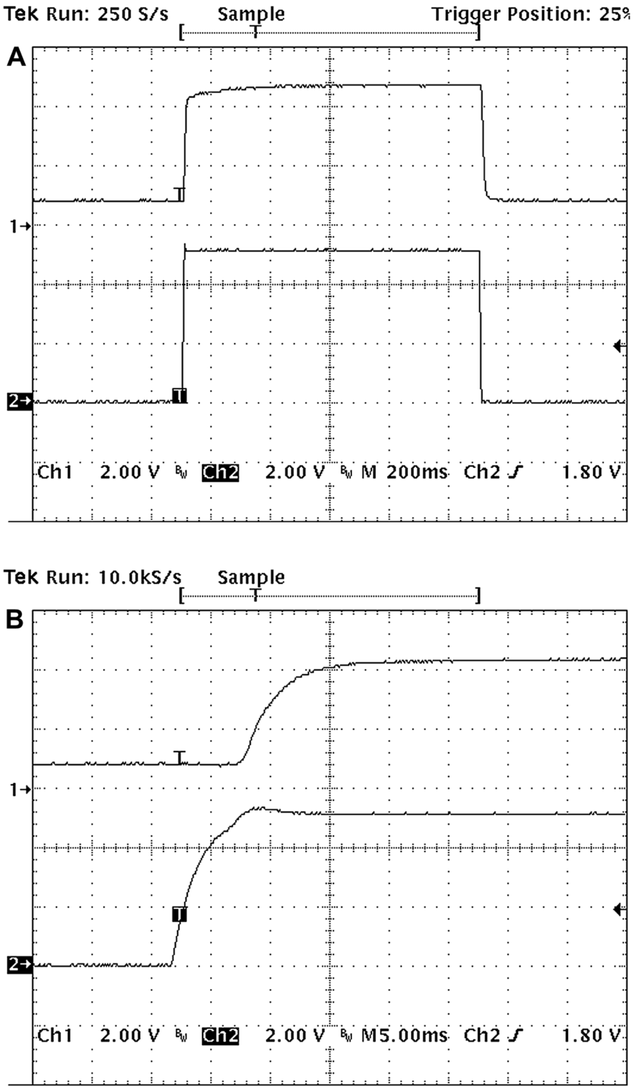

Fig. 4 Air flow at the inlet of a charcoal tube as displayed on an oscilloscope. The control valve is mounted inside a custom sampling head just downstream from the charcoal tube. (A) 200 ms per horizontal division shows actuation and de-actuation. (B) 5 ms per horizontal division verifies the improved dynamics.

de-energized. Twenty five micrometre (μm) screens are required between the charcoal tubes and the valve inlets to protect the valve from any charcoal or other particles that might otherwise enter and damage the valve. A cable running from the PSP case to the sampling head performs double duty. Signals from two wires in the cable control the valve, other wires connect to a sensor that monitors the ambient temperature in the breathing zone. A protective cover is removed to change charcoal tubes (see Fig. 5). A production version could be made smaller and built inside of a more durable molded plastic housing.

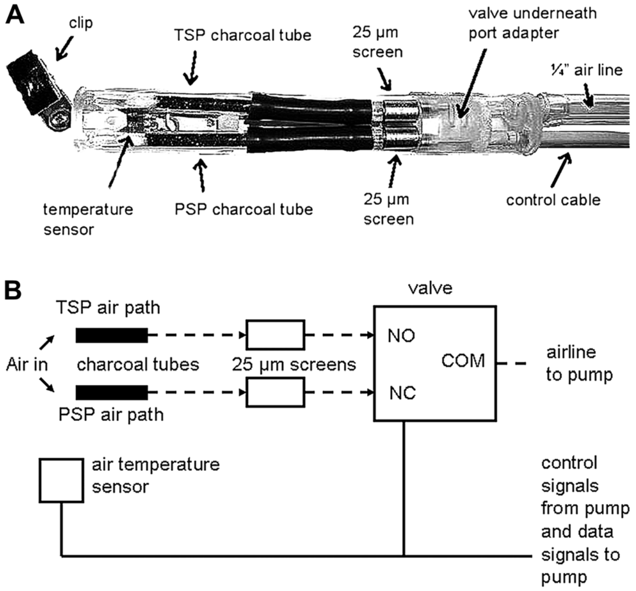

Fig. 5 Custom sampling head. (A) Internal view, (B) functional diagram. NO = normally open port, NC = normally closed port, and COM = common port.

Calibration

PSP and TSP modes require different calibrations. The LCD displays only the calibration menus that are applicable and displays them in the required sequence. Calibrations may be performed before each sampling session, but are only required before the first run of the day and whenever the flow is changed before TSP runs. For PSP mode, if calibration is required, the Setup menu displays four calibrations to be performed in the order; CAL 1, 2, 3, and 4. CAL 1 stores the MAF sensor output voltage after the pump is adjusted to 200 cm^3 min^{-1} flow at STP. Flow is measured through the TSP charcoal tube that is in the custom sampling head. CAL 2, 3, and 4 are valve calibrations performed at 100, 75, and 25 cm^3 min^{-1}, respectively, and are performed through the PSP charcoal tube. With interpolation, these values compensate for any difference between valve actuation and de-actuation times that would otherwise introduce errors into the volume of air sampled. Valve calibration for PSP mode minimizes mean flow error and, since the same valve action taking the same response time occurs independent of the magnitude of change in the effective flow, SD should also be minimal. By calibrating through the PSP and TSP charcoal tubes both flow paths are verified as fully functional. For TSP mode either one or two calibrations are required depending upon the flow that is selected. Since a MAF sensor is used during all calibrations, internal temperature and pressure sensors are used so that standard units may be converted into volumetric units whenever necessary.

Despite the various calibrations, all are performed in the same manner. Each CAL menu displays the flow to which the pump must be adjusted and the type of instrument to use to measure that flow, *e.g.*, a DryCal DC-2 (Bios International Corp., Butler, NJ, USA), a bubble burette, or equivalent standard. The industrial hygienist then connects a length of tubing between the appropriate charcoal tube and the calibration standard. (Note that when using the DryCal DC-2 it must be programmed to match the STP of 0 °C and 1 atm used by the MAF sensor.)

Experimental

Experiments were set up to compare the instantaneous flow and cumulative volume pumped through the PSP's sampling medium to a subject's respiration and to that predicted by a regression equation. A PT monitored the subject's respiration. The PT was constructed by connecting a calibrated Omega Engineering, Inc. (Stanford, CT, USA) PX163-2.5BDV5V differential pressure transducer across an ADInstruments, Inc. (Colorado Springs, CO, USA) MLT300L respiratory flow head which was attached to a Hans Rudolph, Inc. (Shawnee, KS, USA) 7900 series two-way non-rebreathing face mask. A QVS, Inc. (Romulus, MI, USA) CC317Y serial "Y" cable was used between the LifeShirt® system and the PSP to monitor the real time data stream used by the PSP to calculate $\dot{V}_E$. A TSI, Inc. (Shoreview, MN, USA) 4140 Thermal Mass Flowmeter was connected ahead of the PSP charcoal tube to provide a direct verification of flow and cumulative volume through the sampling medium. A Data Translations, Inc. (Marlboro, MA, USA) DT9802 data acquisition module interfaced the analog signals from the PT and the thermal mass flowmeter to a USB port on a desktop computer. Agilent Technologies (Santa Clara, CA, USA) VEE One Lab software stored, processed and displayed ventilation parameters including instantaneous flow and cumulative volume. For each session a comma-delimited text file was generated which included the data from the PT, LifeShirt®, and flow meter.

Preparation for each of three sessions included several steps. The subject's gender, age, height, weight, and resting HR (obtained after the subject sat quietly for 5 min) were entered into the PSP. The PSP was calibrated. The subject put on a LifeShirt® vest, recorder, PSP, sampling head and associated cables. The subject was fitted with the face mask. Once all equipment was interconnected and running, a timer was started and the session began.

There were four consecutive 20 min segments in a session, each segment consisted of 10 min of exercise followed by 10 min of rest. The subject performed step tests, stepping onto, then off of, a 32.5 cm high platform. While stepping up, the subject raised a paint roller in one hand above shoulder height, then lowered it. The arm movements simulated the activity of the worker population selected for upcoming field tests. The subject took 5 steps min^{-1} during the first segment, 10, 15, and 20 steps min^{-1} during the second, third, and fourth segments, respectively.

After these experiments were conducted, timing of the LifeShirt® data streams was measured at NIOSH laboratories. Measurements were made using a Hewlett Packard, Inc. (now Agilent Technologies, Inc., Santa Clara, CA, USA) model HP53131A Universal Counter set up in the time interval mode (Time & Period, T1 to T2, Common 1: ON, gate delay time 0.78 s, 50 ohm inputs with external attenuation, and statistics enabled). Visual confirmation of proper triggering was provided by a Tektronix, Inc. (Beaverton, OR, USA) model TDS360 oscilloscope set for a 200 ms per division time base.

To further characterize PSP performance, a computer program was written to simulate the LifeShirt® system, thereby allowing data sets acquired from human subjects to be replayed through the serial port on the computer to the PSP. One data set was replayed 3 times to verify repeatability of the PSP performance. This data was also run 2 other times, using pseudo parameters for age, gender, height, and weight. Altering these subject parameters caused the rate of change of $\dot{V}_E$ to be proportional to the baseline data on a second by second basis, while holding all other variables constant. Finally, simulations were run with data sets from 3 subjects to provide a direct generalization of performance.

Comparisons were made between the flow commanded by the simulator to that measured using a Honeywell, Inc. (Freeport, IL, USA) model AWM3100V MAF sensor as recorded by a National Instruments (Austin, TX, USA) data acquisition card, model AI-16XE-50. Data was processed by a program written in the Microsoft® Visual Basic® 6.0 language on a laptop computer. Each second, the data acquisition card captured and averaged 1000 samples which allowed direct second by second comparisons to the pump flow updates. The MAF sensor was calibrated at 8 points across the flow range using an air tube. No instrument was available with accuracy good enough to verify the performance of this setup, but accuracy seems to be within at least 0.5%.

The experiments using the PT with human subjects were conducted at Pennsylvania State University (USA) according to the procedures of the Office for Research Protections.

Results

Several comparisons were made to evaluate PSP performance. Cumulative volume recorded by the PSP was in excellent agreement with that measured by the thermal mass flowmeter. Differences ranged from −0.72 to 3.1% and averaged 0.99% (n = 3). Likewise, excellent agreement was found between the (scaled) cumulative volumes recorded by the PSP and those commanded of it by the regression model and LifeShirt® data inputs. Table 1 presents results for each session. The average difference was −2.5% (n = 3) and the associated SD was 0.3. These results suggested a small negative bias.

Analysis revealed that this −2.5% bias was caused by truncation in some calculations by the 24-bit floating point math. The program was revised to use long integer variables to extend calculations to 32 bits. To verify the correction, more data was taken over a 3 hour session and analyzed. The error in cumulative volume was reduced to under 0.2%.

Data was processed on a second by second basis to confirm that the effective flow of the PSP tracked with that commanded. As plotted in Fig. 6, the proximity of data points to the line of identity provides evidence of a highly linear relationship and close agreement.

Comparisons were also made to evaluate performance of the total system, *i.e.*, the LifeShirt® and regression model together with the PSP. Cumulative volume recorded by the PSP agreed very well with the volume inhaled by the subject as measured by the PT. The average difference was 1.5% (n = 3). Table 1 presents results for each session. Moreover, the data was processed on

Table 1 Comparisons of cumulative volumes with percent differences. The scaling factor has been applied to the PSP sample volume

Session	PT vol/L	Model vol/L	PSP vol/L × 350	PSP − PT (%)	PSP − Model (%)
1 (2-12-08)	1660	1810	1760	6.0	−2.8
2 (2-14-08)	1780	1810	1770	−0.6	−2.2
3 (2-20-08)	1950	1980	1930	−1.0	−2.5
Average	1797	1867	1820	1.5	−2.5
Std deviation	146	98	95.4	3.9	0.3

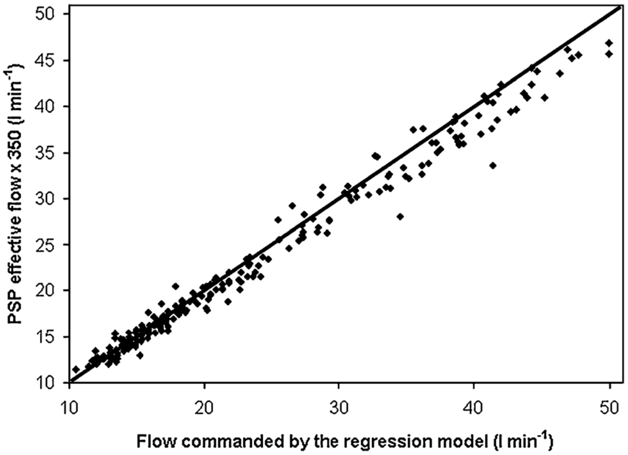

Fig. 6 PSP effective flow tracks well with that commanded by the regression model using LifeShirt® data inputs (every 60th data point plotted for clarity, with line of identity, scaling factor applied, and 3 runs combined). PSP effective flow × 350 = 0.926 × flow commanded by regression model + 1.180, $R^2 = 0.985$.

a second by second basis to confirm that the effective flow of the PSP tracked with the subject's $\dot{V}_E$. The tracking error increased as indicated by the greater scatter around the line of identity (Fig. 7) compared to that for the PSP only (Fig. 6). Despite the larger tracking error, the cumulative volume of air sampled by the PSP deviated 6% or less from the volume inhaled by the subject for all three sessions (PSP scaling factor applied). These results were obtained from the application of the regression model to a single subject for whom the model performs exceptionally well. Performance may vary with other subjects.

In an attempt to further optimize performance, some measurements were made to delineate a specific cause for the increase in scattering. The data streams sent from the LifeShirt® System to the PSP were observed in the laboratory using the Universal Counter and an oscilloscope. The data streams should be sent once per second, but the counter and oscilloscope both showed that, occasionally, the time between transmissions was as short as 0.8 s and as long as 1.4 s. Normally, however, the transmission rate was close to once per second (0.977 s mean; 0.042 SD, $n = 600$). No further changes were made to the system.

Accumulated volume tracked well over the duration of sampling despite any deviation in instantaneous flow. Accumulated volume is plotted in Fig. 8.

Simulations also verified excellent performance. Performance was found to be repeatable. When the same data set was run 3 times, the 60 s averages for flow were 0.3%, 0.7%, and 0.2% below that commanded by the simulator, and the cumulative volumes were 0.8%, 0.4%, and 0.8% more than that commanded. The coefficient of variation (CV) in the flow was 0.3 for all 3 runs (for each run $n = 4889$). Performance was found to be essentially independent of the magnitude of change in $\dot{V}_E$. When subject parameters were altered resulting in CVs of 0.5 and 0.2 ($n = 4889$ for both runs), the 60 s averages for flow were both 1.7% above that commanded, while the cumulative volumes deviated 0.8% and −0.6%, respectively. Finally, results from 2 other subjects were compared to data from the first subject. Performance was considered generalizable as 60 s averages of flow were 1.6%, 1.7%, and −0.3%, and cumulative volumes were −0.4%, 0.6%, and 0.8%, from that commanded, with CVs of 0.3 ($n = 4950$), 0.4 ($n = 4956$), and 0.3 ($n = 4889$), respectively. Truncation in computer calculations, which is inherent due to bit size limitations in computer processors and associated memory, accounts for some error, and may provide an explanation for why some runs had average flow errors that were slightly negative while having slightly positive cumulative volume errors.

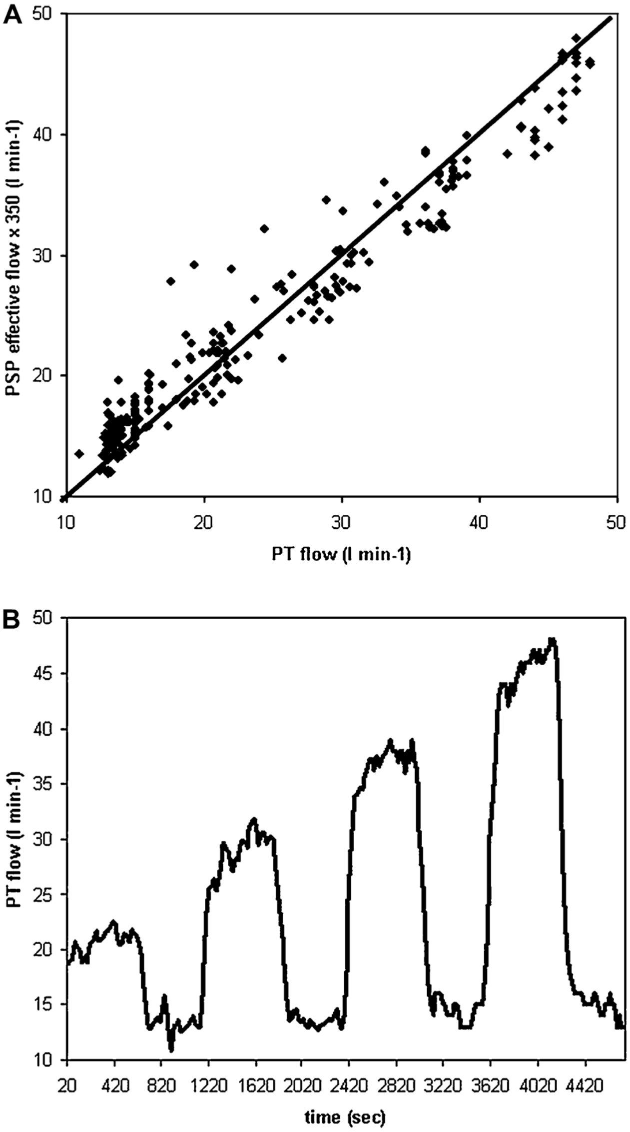

Fig. 7 Plots for Session 3. (A) PSP responds well to Vi_E of subject as measured by PT (every 20th data point plotted for clarity, with line of identity, and scaling factor applied). PSP effective flow × 350 = 0.905 × PT flow + 2.534, $R^2 = 0.954$, (B) typical Vi_E timeline.

Conclusion

A novel approach to PSP design that overcomes the limitations of prior work has been described. By controlling flow with a valve that has been integrated into a sampling head, response time of the PSP is, for practical purposes, mutually exclusive of the magnitude of changes in the effective flow, thereby

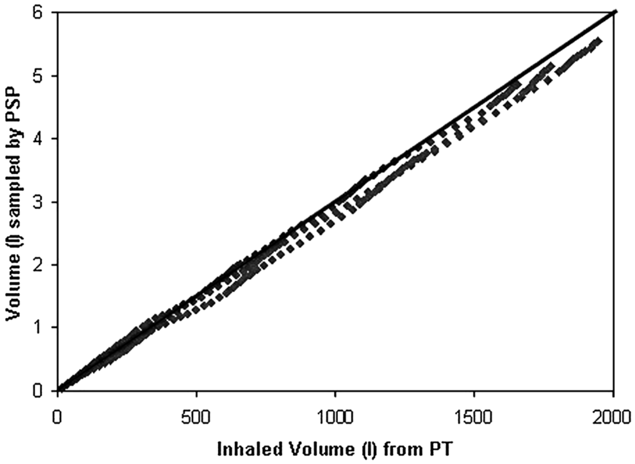

Fig. 8 Comparison of accumulated volumes. Volumes sampled by the PSP tracked well with that inhaled by the subject (PT) over the entire sampling sessions (every 60th data point plotted for clarity, with line of identity, runs 1–3 combined). Volume sampled by PSP = 1/352 × Inhaled volume (PT) − 0.0174, $R^2 = 0.997$.

facilitating consistently small error in performance irrelevant of the exertion scenario. Data confirms excellent performance when used with a LifeShirt® System to estimate $\dot{V}_E$. Since the NIOSH PSP may be reprogrammed to accept a variety of data inputs, advances in technology for estimating $\dot{V}_E$ in real time may be leveraged. The combination of these features gives the NIOSH PSP the potential of following inhalation on a breath by breath basis.

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