HETA 96-0060-2632
Cincinnati Sportsmedicine and Orthopaedic Center
Cincinnati, Ohio

Alan Echt, CIH
G. E. Burroughs, CIH
Steven W. Lenhart, CIH
Donald E. Booher

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

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ACKNOWLEDGMENTS AND AVAILABILITY OF REPORT

This report was prepared by Alan Echt, of the Hazard Evaluations and Technical Assistance Branch, Division of Surveillance, Hazard Evaluations and Field Studies (DSHEFS) and G. E. Burroughs, of the Methods Research Branch, Division of Physical Sciences and Engineering (DPSE). Field assistance was provided by Steven W. Lenhart and Donald E. Booher. Desktop publishing was done by Kate Marlow.

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Health Hazard Evaluation Report 96-0060-2632
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Alan Echt, CIH
G. E. Burroughs, CIH
Steven W. Lenhart, CIH
Donald E. Booher

SUMMARY

The National Institute for Occupational Safety and Health (NIOSH) received a management request for a health hazard evaluation (HHE) on January 5, 1996, from a physician with the Cincinnati Sportsmedicine and Orthopaedic Center (CSMOC) in Cincinnati, Ohio. Technical assistance was requested in evaluating carbon dioxide (CO_2) exposures among surgeons, nurses, and other operating room personnel performing or assisting with surgical procedures while wearing surgical isolation suits. CSMOC employees had reported headache, discomfort, irritability, and sweating while wearing the suits. NIOSH investigators, working in collaboration with physicians at CSMOC, measured CO_2 concentrations inside suit helmets (also known as surgical helmets) during an experimental exercise protocol designed to model the work of orthopedic surgery. Four types of surgical helmets were tested from those manufactured by three companies. In addition, two NIOSH-approved powered air-purifying respirators (PAPRs) were tested. Mean CO_2 concentrations during the 15-minute tests ranged from 5,500 parts per million (ppm) to 11,700 ppm. The NIOSH recommended exposure limit (REL) for carbon dioxide is 5,000 ppm as a time-weighted average (TWA) for up to a 10-hour workday, with a short-term exposure limit (STEL) of 30,000 ppm. The Occupational Safety and Health Administration's (OSHA) permissible exposure limit (PEL) is an 8-hour TWA of 5,000 ppm. The American Conference of Governmental Industrial Hygienists' (ACGIH®) Threshold Limit Value (TLV®) is 5,000 ppm as an 8-hour TWA, with a STEL of 30,000 ppm. The results of this HHE indicate that if these surgical helmets and PAPRs are used during operations lasting eight hours or more, the users will be exposed to CO_2 levels in excess of the 8-hr TWA exposure limits. For the highest mean CO_2 concentration measured (11,700 ppm), a user would be overexposed if a procedure lasted 3.5 hours or longer.

NIOSH investigators measured high concentrations of carbon dioxide during the experimental exercise protocol. The measured levels did not exceed the STEL exposure criteria. However, if this exercise protocol is similar to actual orthopedic surgery, the results indicate that 8-hr TWA exposure limits may be exceeded for the surgical helmets investigated in the survey. Recommendations to reduce the symptoms reported by employees are provided in the Recommendations section of this report.

Keywords: SIC 8011 (Offices and Clinics of Doctors of Medicine), carbon dioxide, CO_2, PAPR, powered air-purifying respirator, orthopedic surgery, surgical helmets, surgical isolation suits.

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INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) received a management request for a health hazard evaluation (HHE) on January 5, 1996, from a physician with the Cincinnati Sportsmedicine and Orthopaedic Center (CSMOC) in Cincinnati, Ohio. Technical assistance was requested in evaluating carbon dioxide (CO_2) exposures among surgeons, nurses, and other operating room personnel performing or assisting with surgical procedures while wearing surgical isolation suits. Operating room personnel had complained about headaches, irritability, discomfort, and sweating while using the suits. NIOSH investigators, working in collaboration with physicians at CSMOC, measured CO_2 concentrations inside suit helmets (also known as surgical helmets) during an experimental exercise routine. The exercise protocol was designed to simulate the effort required during orthopedic surgery. A simulation was performed because the surgeons were concerned that testing the helmet atmosphere during surgical procedures might prolong the operations, thus increasing the patient's risk of infection.

BACKGROUND

Surgical isolation suits were introduced in orthopedic surgery to prevent the infection of patients by operating room personnel.[1] One study showed a 750-fold reduction in the average airborne concentration of bacterial particles during total hip implants when total body exhaust clothing was used in conjunction with a vertical laminar flow ventilation system in an operating room.[2] However, further studies have shown that the use of UVC light and occlusive clothing resulted in a further reduction in the airborne bacteria concentration compared to the use of surgical isolation suits and that UVC is less expensive than the use of isolation suits.[3,4] Test subjects were asked to perform light exercise (<4 kilocalories/minute), approximating the effort of home- repair carpentry or brick laying, while standing at an upper extremity ergometer

Concerns about the potential transmission of blood-borne pathogens from infected patients to health care providers through the inhalation of aerosols, especially during orthopedic procedures (where surgical hand and power tools, including drills, hammers, chisels, reamers, bone saws, and electrocautery are used) have re-emphasized the need for contamination control.[5,6] These concerns were heightened when the human immunodeficiency virus was demonstrated to remain viable in cool aerosols generated by certain surgical power tools.[7] According to the HHE requester, these concerns have resulted in the widespread use of surgical isolation suits during orthopedic surgery.

The helmet portion of a surgical isolation suit (surgical helmet) typically consists of a helmet frame with a disposable cover, a window which may or may not be an integral part of the cover, air filters for the inhaled and exhaled air, and one or more fans. Surgical helmets are similar to powered air-purifying respirators (PAPRs), but they are not NIOSH-certified respirators. An industrial hygiene consultant for a surgical helmet manufacturer measured CO_2 concentrations approaching the Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) of 5,000 parts per million (ppm) while monitoring standing subjects and exceeding the PEL during exercise.

METHODS

Exercise Protocol

A brief questionnaire was administered to all study participants to assess the potential for risk to their health from participating in the exercise protocol. A yes response to any of the questions resulted in further investigation by a NIOSH physician to determine whether the individual should participate in the study.

(Uppercycle model 841, Engineering Dynamics Corp, Lowell, MA).[8,9] The ergometer was set at a workload of 20 Watts, and the subjects were asked to maintain an exercise rate of 60 revolutions per

minute (rpm) on the ergometer's hand cranks. This exercise level was intended to be no more demanding than the work of orthopedic surgery, which may involve the use of hand or power tools (e.g., hammers, chisels) during operations such as hip or knee joint replacement. Subjects wore typical surgical clothing for CSMOC (i.e., a surgical gown) with 1) no helmet, 2) with each of the four surgical helmets available to this medical practice, and 3) with two NIOSH-approved PAPRs with high efficiency particulate air (HEPA) filters. An exercise test would have been halted if a measured CO_2 concentration reached the NIOSH short-term exposure limit (STEL) of 30,000 ppm, or when the CO_2 in the helmet reached a steady state for a period of five minutes. A trial was halted if a CO_2 concentration in a helmet did not reach the NIOSH STEL or a steady state after fifteen minutes. Subjects rested between exercise periods for as long as it took for their heart rate, blood oxygen saturation, and oral temperature to return to baseline values, or for as long as the duration of the exercise period which preceded the rest period, whichever was longer.

Biological Monitoring

Heart rate and blood oxygen saturation were measured with a pulse oximeter (Ohmeda Biox 3740). This gauged the effect of the different surgical helmets on the cardiovascular system at equal levels of physical exertion. The probe was attached to the test subject's left index finger. Because a subject's arm motion affected the instrument's performance, subjects held their left hand up every two minutes while continuing to exercise with their right arm, and kept it up until a stable reading was attained. Body temperature was measured before and after each trial with an oral thermometer. Measuring oral temperature indicated whether wearing a surgical helmet or PAPR placed an individual at increased risk of heat stress compared with the exercise protocol alone. The "no helmet" condition was always the first test performed by a subject, but the order of helmets tested was varied.

Study Participants

The study participants were two orthopedic surgeons and two NIOSH investigators. Participation in this study was voluntary, and a signed informed consent form was obtained from each subject. Participants had access to information about the study via an information sheet distributed prior to the study.

Environmental Monitoring

Carbon dioxide measurements were made using a Gastech Model RI-411A portable infrared (IR) indicator (Gastech, Inc., Newark, CA). This instrument is battery powered, weighs approximately 2.6 kilograms (kg), and is 23 centimeters (cm) wide, 19 cm high and 11 cm deep. It is a chopped, single beam non-dispersive IR analyzer which monitors absorbance of CO_2 in a selected (unspecified) narrow frequency range. An internal pump continuously draws sample air through the detection chamber where absorbance is measured, compared with a background signal, and converted to an output signal used to show CO_2 concentration on an LCD display. The output signal can also be sent to an analog data collection device for storage. Normal instrument range is 0 to 4975 ppm (parts per million by volume) CO_2 in air, with the instrument reading in 25 ppm increments.

For the purposes of this study, the sample air stream was diluted by drawing the total sample from two legs of a "T" as shown in Figure 1. Two Hastings model CPR-4SA mass flow controllers (Teledyne Hastings-Raydist, Hampton, VA) were used to adjust the flow of the contaminant air stream drawn from the sample site and the diluent stream drawn from ambient air. Ambient air was drawn through a scrubber containing Ascarite II (Thomas Scientific, Swedesboro, NJ) to remove CO_2. Scrubbed air was then mixed with the contaminant stream coming from the surgical helmet system being tested before being drawn into the CO_2 indicator.

Dilution of the contaminant air stream in a ratio of 1 : 9 with scrubbed ambient air enabled the analytical range of the assembled instrumentation package to be extended from 4,950 ppm to 49, 500 ppm, measured in 250 ppm increments; no measurements or calibrations were made above 20,000 ppm. A multi-point calibration of the assembled analytical instrumentation was conducted in the laboratory and validated on-site using standards prepared by injecting known volumes of pure CO_2 (Air Products and Chemicals, Inc., Allentown, PA) into known volumes of room air using 50 milliliter (ml) and 1 Liter (L) syringes (Hamilton, Inc., Reno, NV). A zero setting was accomplished by adding a second CO_2 scrubber to the contaminant stream inlet to eliminate CO_2 from both the contaminant and diluent legs of the "T". Combined data from on-site and pre- and post-calibration produced a correlation coefficient of 0.971 for 110 data points.

The CO_2 concentration in room air was monitored continuously during all testing using a second, non-diluted CO_2 analyzer. This second monitor was calibrated using a commercial span gas (Alphagaz, Cambridge, MD). Continuous voltage output (corresponding to CO_2 concentration) from both analyzers was sent to Metrosonics Model DL3200 dataloggers (Metrosonics Inc., Rochester, NY) for data storage. These data were subsequently downloaded to a personal computer. The helmet CO_2 concentration was recorded every two minutes during the exercise trials, and the room CO_2 concentration was recorded by an investigator before and after each trial.

EVALUATION CRITERIA

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for the assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects even though their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary sources of environmental evaluation criteria for the workplace are: (1) NIOSH recommended exposure limits (RELs)[10], (2) the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLVs)[11] and (3) the U.S. Department of Labor, OSHA PELs.[12] In July 1992, the 11th Circuit Court of Appeals vacated the 1989 OSHA PEL Air Contaminants Standard. OSHA is currently enforcing the 1971 standards which are listed as transitional values in the current Code of Federal Regulations; however, some states operating their own OSHA approved job safety and health programs continue to enforce the 1989 limits. NIOSH encourages employers to follow the 1989 OSHA limits, the NIOSH RELs, the ACGIH TLVs, or whichever are the more protective criterion. The OSHA PELs reflect the feasibility of controlling exposures in various industries where the agents are used, whereas NIOSH RELs are based primarily on concerns relating to the prevention of occupational disease. It should be noted when reviewing this report that employers are legally required to meet those levels specified by an OSHA standard and that the OSHA PELs included in this report reflect the 1971 values.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits (STEL) or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from higher exposures over the short-term.

Carbon Dioxide

Carbon dioxide is a simple asphyxiant and a potent stimulus to respiration. It is both a depressant and excitant of the central nervous system.[13] Carbon dioxide is a normal constituent of air at a concentration of about 300 ppm.[14] As the concentration of CO_2 in inspired air increases, the alveolar to capillary ratio of CO_2 decreases, rendering normal diffusion of CO_2 from the blood less favorable.[15] The body compensates by an increase in respiratory depth and rate and an accompanying increase in cardiac output.[15]

After several hours of exposure to CO_2 at a concentration of 20,000 ppm, exposed subjects develop headache and shortness of breath on mild exertion.[13] The headache becomes progressively more severe at 30,000 ppm, diffuse sweating occurs, and shortness of breath will exist even at rest.[15] Chronic exposures to increased CO_2 concentrations produce widespread physiologic alterations, including acidosis and adrenal cortical exhaustion following prolonged, continuous exposures to 10,000 to 20,000 ppm.[15] However, adaptation to levels ranging from 15,000 to 30,000 ppm has occurred with chronic exposure.[13] The NIOSH REL for carbon dioxide is 5,000 ppm as a TWA for up to a 10-hour workday, with a STEL of 30,000 ppm. The OSHA PEL is 5,000 ppm, 8-hour TWA. The ACGIH TLV is 5,000 ppm as an 8-hour TWA, with a STEL of 30,000 ppm.

RESULTS AND DISCUSSION

Four types of surgical helmets were evaluated from among those manufactured by three companies: The Stackhouse Freedom Mark, the Stackhouse Freedom-Aire, the Stryker Steri-shield, and a helmet manufactured by DePuy. The two PAPRs evaluated were the Racal Air-Mate HEPA 10 (TC-21C-635) and the 3M Belt-Mounted PAPR Snapcap Hood System with HEPA filter (TC-21C-671). The surgical helmet systems were categorized by design (self-contained unit with internal fans or helmet with belt-mounted fans and hoses) and by ventilation pattern (inflow alone, or inflow with exhaust). The surgical helmet systems could all be modified by changing the external fan direction, fan speed, or number of hoses connected to the fans. Each system tested was classified by these modifications. The Freedom Mark system with belt-mounted fans was classified as either "shark" or "ram" (because of its appearance) based on the number of hoses connected to each fan, and the pattern of hose placement on the helmet (top or bottom ports, on both left and right front of the helmet). The 11 surgical helmet configurations tested were based upon recommendations to CSMOC physicians by sales representatives, manufacturers' literature, or operating room personnel. No other modifications or alterations were made to any system. Surgical helmets tested were selected from operating room inventory or provided by sales representatives.

The results of the tests are presented in Table 1. For each of the 11 surgical helmet systems and two PAPRs tested, the means in the table resulted from averaging the means of four tests. The maximum and minimum values reported represent the maximum and minimum of all four tests for that particular surgical helmet configuration or PAPR. Mean CO_2 concentrations ranged from 5,500 ppm to 11,700 ppm. These results indicate that if these surgical helmets and PAPRs are used during operations lasting eight hours or more, the users will be exposed to CO_2 levels exceeding the 8-hr TWA exposure limits. For the highest mean CO_2 concentration measured (11,700 ppm) a user would be overexposed if a procedure lasted for 3.5 hours or longer. Three of the four subjects did report headaches following several hours of trials.

The concentration of CO_2 in room air ranged from 375 ppm to 575 ppm, with a mean of 450 ppm. The mean difference between pre- and post-test oral temperatures was 0.2°C. In 12 of 56 instances, the oral temperature dropped during the trial. The maximum decrease was 0.9°C. In three cases, oral temperature rose more than 1°C. In one case, this increase was 2°C (from 35 to 37°C). However, the oral temperature did not exceed 38°C in any of the trials. Therefore, no heat strain was noted as a result of using either the surgical helmets or PAPRs. The difficulty encountered in the use of the pulse oximeter on a hand in motion in the beginning of this study precludes the report of the measurements obtained with it.

CONCLUSIONS

None of the CO_2 concentrations measured during any of the 15-minute tests exceeded the STEL of 30,000 ppm. However, the results of this HHE do indicate that wearing a surgical helmet or NIOSH-approved PAPR during orthopedic surgical procedures may result in a user being overexposed to CO_2, depending on the duration of surgery. The results of this study agree with the results of a previous laboratory study of the performance of positive pressure powered respirators.[16] While the CO_2 concentrations noted in this study have not been associated previously with adverse health effects, they may explain the symptoms reported by the employees at CSMOC and experienced by three of the test subjects. The effects of these exposures in combination with other airborne contaminants in operating rooms, such as waste anesthetic gases, vapors from adhesives used in joint replacement, and fumes from electrocautery are unknown.

RECOMMENDATIONS

The following recommendations may help reduce symptoms of headache, discomfort, irritability, and sweating by CSMOC employees during surgical procedures.

1. The most comfortable helmet should be selected among those configurations which result in the lowest mean carbon dioxide concentration. OSHA regulations require the use of NIOSH-approved respirators where these are available. None of the surgical helmets tested have this approval.

2. The manufacturers of the non-NIOSH approved devices used in this evaluation should submit their surgical helmets to NIOSH approval testing. Once approved by NIOSH, these systems could then be used with confidence that the helmets' components met the minimum requirements for safe and effective protection from infectious agents.

3. Respirator manufacturers should work with physicians to develop respirators that meet the needs of orthopedic surgeons for comfort, visual and auditory acuity, and ease of use. Other health care professionals who use surgical helmets should also take part in development of these products.

4. Additional studies should be conducted to evaluate the CO_2 exposures that occur during actual orthopedic procedures. These studies should also evaluate exposures to other air contaminants present during surgery (e.g., waste anesthetic gasses, vapors from adhesives).

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Table 1
Results of Four Tests of Each Configuration of Surgical Helmet and PAPR
In Parts Per Million of Carbon Dioxide
Cincinnati Sportsmedicine and Orthopaedic Center
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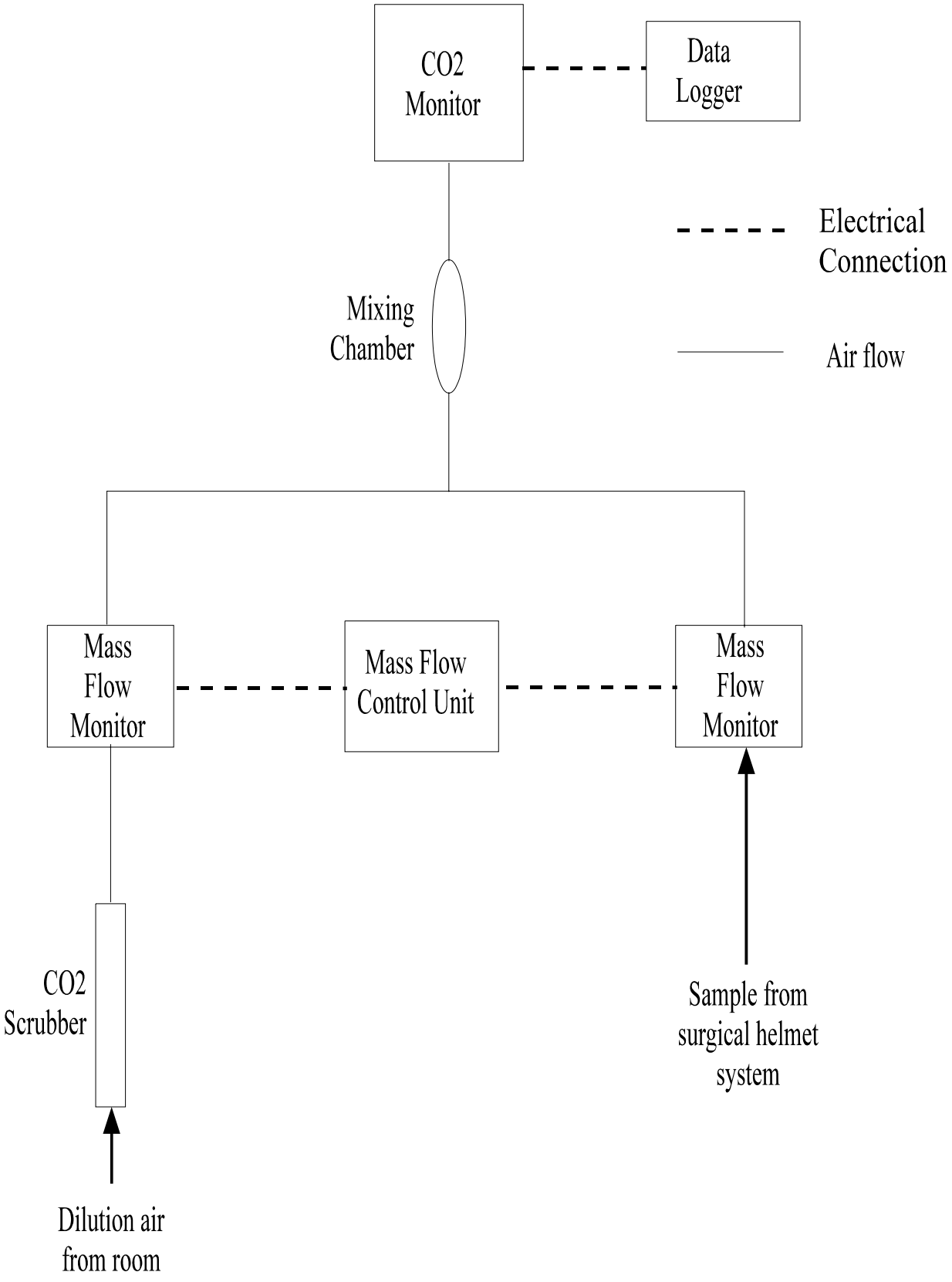
	Surgical Helmet System											PAPR	
	Stackhouse							Depuy		Stryker		3M	Racal
	Shark		Ram			FreedomAire							
	High	Low	In and Out		In High	High	Low	In and Out	In only	High	Low		
			High	Low									
Minimum	6,500	5,550	4,000	2,250	2,600	3,000	2,800	1,700	3,650	7,950	6,200	2,150	7,000
Maximum	11,300	11,700	13,100	28,450	9,000	7,750	9,750	13,200	9,200	16,300	16,000	9,000	12,500
Mean	9,300	9,800	10,200	11,100	5,700	5,500	6,600	7,600	6,200	11,200	11,700	5,700	9,700

Notes: PAPR means powered air-purifying respirator
High means that where the fan setting was adjustable, the high speed setting was selected
Low means that where the fan setting was adjustable, the low speed setting was selected
In means that the fan(s) supplied room air to the surgical helmet
Out means that the fan(s) removed exhaled air from the helmet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Scrubber
Sample from
surgical helmet
system
Dilution air
from room

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