Low Flow/Optimized Flow Oxygen Systems for Passengers

Data Collection

What data will you collect or create?

The anticipated data that will be generated from this research project include:

  De-identified research participant demographic, medical history, numerical data sets (raw [LabVIEW .tsv files and HansRudolph SmartLab .txt files] and aggregate data [Excel .xlsx files]).

LabVIEW data:

DAQ Time
Note Bit - marker
Note Text - notes made during chamber flight
HnsR Sp02 (%) - HnsR data indicates that it was pulled from HansRudolph
HnsR Altitude (ft)
HnsR Abs. Pressure (psia)
HnsR Abs. Pressure (mmHg)
n/c
Am6 Chamber (psia) - additional Omega pressure sensor inside chamber
Am6 Chamber (mmHg) - same
Am6 Atmo (psia) - additional Omega pressure sensor outside chamber
Am6 MFC (nlpm) - passenger oxygen supply, mass flow controller
Am6 FM1 (nlpm) - passenger oxygen supply, flow meter (outside chamber)
Am6 FM2 - Chamber (lpm) - passenger oxygen supply, flow meter (inside chamber)
MGA1 %N2
MGA1 %O2
MGA1 %Co2
MGA1 %Ar
MGA2 %N2
MGA2 %O2
MGA2 %Co2
MGA2 %Ar
NTPD - MFC Setpoint (slpm) - passenger oxygen supply, mass flow controller setpoint
HR Subject (BPM) - heart rate of Subject via H10 Polar strap
HR IO 1 (BPM) - heart rate of Inside Observer via H10 Polar strap
HR IO 2 (BPM) - heart rate of 2nd Inside Observer (if attending or if 1st strap failed) via H10 Polar strap
45k-T - time at 45K feet indicated by a marker in a row, each mark = 40ms (25Hz)
40k-T
35k-T
30k-T
25k-T
20k-T
18.5k-T
15k-T
12k-T
HnsR Sp02 (vdc) - raw voltage
HnsR Altitude (vdc) - raw voltage
HnsR Abs. Pressure (vdc) - raw voltage
HnsR Abs. Pressure (calc) - pressure sensor data

n/c

Am6 Chamber (A) - Remaining data from here to beginning of HansRudolph data were extracted from the chamber control computer (less accurate, used as verification in a qualitative manner)

Am6 Chamber (calc)

Am6 Atmo (A)

Am6 MFC (vdc)

Am6 FM1 (vdc)

Am6 FM2 - Chamber (vdc)

vdc - MFC Setpoint

Chamber Time

Chamber.ain.ChamPressure

Chamber.ain.AmbientPressure

Chamber.ain.AccumulatorPressure

Chamber.ain.ChamTemperature

Chamber.ain.ChamHumidity

Chamber.AmbientAltitude

Chamber.ChamberAltitude

Chamber.AccumulatorAltitude

HansRudolph Data: (some of which only populated during pneumotach use and/or expansion strap use)

Session Time

Raw Flow

Filtered Raw Flow

Current Volume

Breaths Per Minute

I:E Ratio

Inhale Volume

Average Flow

Corrected Flow

Filtered Corr. Flow

Inhale

Exhale Volume

Peak In Flow

Peak Ex Flow

Leak

Minute Volume

Inhale Minute Volume

Inhale Time

Exhale Time

Time to Peak Inhale

Time to Peak Exhale

Total Inhale Volume

Total Exhale Volume

Total Inhale Time

Total Exhale Time

Time Since Reset

Breaths Since Reset

Abs. Pressure

Altitude

Scaled Abdomen - expansion strap

Scaled Thorax - expansion strap

Scaled Combined - expansion straps combined

Heart Rate - per finger sensor

SpO2 - per finger sensor

Breathing rate, breathing minute volume, heart rate, blood oxygen saturation (SpO2) via near infrared sensor, hypobaric chamber pressure-altitudes, & time parameters were either directly extracted or calculated from HansRudolph data.

LabVIEW was necessary mostly due to passenger oxygen system control function, yet was utilized to collect backup data as well.

Within each compiled data Excel spreadsheet available in the repository, Subject ID (CAMI #1-#16), gender, age, height, weight, BMI, Hct, Hgb, heart rate, and base line SpO2 at 10K' and 14K' information appears within the top 6 lines.

 Technical report with recommendations summarizing the data analysis and results.

How will the data be collected or created?

The methods used for creating the data will include computer-based software unique to respective instrumentation. LabVIEW programming will facilitate data acquisition at an appropriate rate (25Hz).

Data collection is projected to be completed within FY25. Each research Subject will experience one flight profile during one visit to the hypobaric chamber. Data generated will be stored on a CAMI research computer. Data will be "backed up" on a weekly basis to an official FAA IT protected and distributed 128GB SanDisk Ultra Flair USB 3.0 Flash Drive. Data will be externally transferred at the conclusion of the study

Documentation and Metadata

What documentation and metadata will accompany the data?

Describe how will the metadata be managed and stored.

Metadata will be managed by the FAA/CAMI Principal Co-Investigators and stored on secure government furnished equipment. Once the research project is complete, the de-identified aggregate datasets and final technical report will be transferred to the National Transportation Library for permanent, long-term storage and public access.

Indicate what tools or software is required to read or view the data.

A computer, or other internet-connected electronic device, with Microsoft Office applications (e.g., Word,

Excel) and Adobe PDF Reader will be required to access the data sets and technical reports. .txt and .tsv files can be opened with MS Excel and saved as an Excel spreadsheet file.

Describe your quality control measures.

At the end of a data collection day, the FAA/CAMI Principal Co-Investigators and/or government trained research support staff, will perform quality control checks of the raw data generated. The FAA/CAMI Principal Co-Investigators will ensure that the final datasets and technical report are maintained and retained on government furnished equipment in accordance with Department of Transportation (DOT) and FAA data

accessibility policies. The FAA/CAMI Co-Investigators will ensure that the files open and have retained the entered data.

Ethics and Legal Compliance

How will you manage any ethical issues?

All de-identified aggregate data, study results, and final technical report will be made publicly available through the National Transportation Library website, as well as through a link on the Civil Aerospace Medical Institute (CAMI) website.

§ Indicate whether the data contain private or confidential information. If so:

§ Discuss how will you guard against disclosure of identities and/or confidential business information.

De-identified, aggregate data will not contain private or confidential information.

§ List what processes you will follow to provide informed consent to participants.

Informed Consent documents were accepted and authorized by the FAA Civil Aerospace Medical Institute (CAMI) IRB following ethical and legal review. Those authorized documents will be utilized with no alterations for distribution to potential participants in order that they are given the opportunity to fully understand the research in which they may be interested in taking part.

Furthermore, before signing, each potential participant will **be consented**, a process that involves a verbal explanation of the research protocol and the rights of the Subject. Only when the Subject is assessed for a full understanding and have signed the appropriate Informed Consent document will they be given the opportunity to enroll and participate as a human research Subject in this Low Flow Oxygen System protocol.

§ State the party responsible for protecting the data.

During collection and up until transfer, the Principal Investigator Dr. James Campbell, Ph.D. is responsible for protecting the data.

§ Discuss how will you guard against disclosure of identities and/or confidential business information. – Only potential research participants who volunteer for the study and who meet the study inclusion criteria, will be allowed to sign the Informed Consent form. This will be the only form on which research participants will identify themselves by name. Only the FAA/CAMI Principal Co-Investigators and government trained research support staff, will have access to the "Master Key" linking an Informed Consent form with an assigned research participant's unique identifier. The "Master Key" and scanned Informed Consent forms will be stored on secure government furnished equipment. The demographic surveys will have input fields only for the research participant's unique identifier. The final datasets for public access will contain mostly aggregate data yet potential exists for presentation of de-identified individual data.

§ List what processes you will follow to provide informed consent to participants. – Only potential research participants who volunteer for the study and who meet the study inclusion criteria, will be allowed to sign as

Human Research Subjects for this protocol. The Informed Consent Form will provide the participant with an overview of the study, the purpose of research, duration of study, any risks or discomfort that may be experienced, potential benefits, confidentiality, medical care for research-related injury, its voluntary nature, contact information in the event of participant questions, the option to unenroll at any time, the potential for removal from an investigator at any time regardless of participant consent, and how the FAA will use the study results. All participants must provide their informed consent prior to any testing.

§ State the party responsible for protecting the data. -- The FAA/CAMI Principal Co-Investigators will be responsible for protecting the data in accordance with FAA data management policies and procedures.

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

Indicate who holds the intellectual property rights to the data.

The Federal Aviation Administration (FAA) holds the intellectual property rights to this data.

List any copyrights to the data. If so, indicate who owns them.

The datasets and technical report are in the public domain.

Discuss any rights be transferred to a data archive.

Any rights to be transferred to a data archive are unknown at this time.

Describe how your data will be licensed for reuse, redistribution, and derivative products.

The data will be available to the public for reuse, redistribution, and the creation of derivative products in accordance with Department of Transportation and Federal Aviation Administration policy regarding U.S. government funded research products (i.e., the data are in the public domain and may be re-used without restriction, with source citation appreciated).

Storage and Backup

How will the data be stored and backed up during the research?

During the data collection and analysis phases, the data will be temporarily stored on a secure government furnished computer, and on a US Government provided and protected USB 3.0 flash drive, prior to being sent to an archive.

How will you manage access and security?

The data security and integrity will be maintained by the Federal Aviation Administration, and the data management and protection will be subject to the standards and methodologies used by the Administration.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Long-term data security and integrity will be maintained by the National Transportation Library (NTL) and the data management and protection will be subject to the standards and methodologies used by the NTL. Datasets include all that are relevant to the statistical analysis as well as descriptive analyses of the OFOS project.

What is the long-term preservation plan for the dataset?

Long-term data security and integrity will be maintained by the National Transportation Library (NTL) and the data management and protection will be subject to the standards and methodologies used by the NTL.

Data Sharing

How will you share the data?

Data will be de-identified and readily available online withing the NTL:

It is understood that the National Transportation Library complies with the following attributes:

1. Promotes an explicit mission of digital data archiving;

2. Ensures compliance with legal regulations, and maintains all applicable licenses covering data access and use, including, if applicable, mechanisms

to protect privacy rights and maintain the confidentiality of respondents;

3. Has a documented plan for long-term preservation of its holdings;

4. Applies documented processes and procedures in managing data storage;

5. Performs archiving according to explicit work flows across the data life cycle;

6. Enables the users to discover and use the data, and refer to them in a persistent way through proper citation;

7. Enables reuse of data, ensuring appropriate formats and application of metadata;

8. Ensures the integrity and authenticity of the data;

9. Is adequately funded and staffed, and has a system of governance in place to support its mission; and

10. Possesses a technical infrastructure that explicitly supports the tasks and functions described in internationally accepted archival standards like Open Archival Information System (OAIS).

Are any restrictions on data sharing required?

Only de-identification is required which will be performed long before upload to the NTL.

Responsibilities and Resources

Who will be responsible for data management?

Re-Use, Redistribution, and Derivative Products Policies:

These data are managed by the Department of Transportation, Federal Aviation Administration. The data are in the public domain and may be re-used without restriction. Citation of the data is appreciated. Please use the following recommended citation:

Campbell, J.E., Jay, S.M. (2025). Optimized Flow Oxygen Systems for Airline Passenger Safety. (Report No. DOT/FAA/AM-25/**25**). Federal Aviation Administration.

Indicate who holds the intellectual property rights to the data.

The Federal Aviation Administration (FAA) holds the intellectual property rights to this data.

What resources will you require to deliver your plan?

CAMI in-house research computers, one flash drive, and an FAA network connected computer will be adequate to hold and transfer all data when necessary.

Planned Research Outputs

Data paper - "Campbell, J.E., Jay, S.M. (2025). Optimized Flow Oxygen Systems for Airline Passenger Safety. (Report No. DOT/FAA/AM-25/52). Federal Aviation Administration."

A Technical Report will be generated at the conclusion of testing. Guidance to sponsor will be delivered.

Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
Campbell, J.E., Jay, S.M. (2025). Optimized Flow O ...	Data paper	2025-09-29	Open	National Transportation Library		Creative Commons Attribution 4.0 International	None specified	No	No