PARTICIPATION INFORMATION SHEET AND CONSENT FORM

Your child / ward is being invited to participate in a research study. His / her participation in this study is entirely voluntary. Before your child / ward takes part in this research study, the study must be explained to you and your child / ward, and you and your child / ward must be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction. Please read carefully the information provided here. If you agree to allow your child / ward to participate, please sign the consent form. You will be given a copy of this document.

STUDY INFORMATION

Study Title:

A study to explore the physiological impact of AIR+ KN95 Masks on children

Principal Investigator:

Eugene Loy
Business Development Manager
Respiratory Protection
Urban Environment Solutions
ST Engineering Innosparks Pte. Ltd.
10 Tampines North Drive 4, #05-07
Singapore 528553
Contact No: (+65) 6873 2074

Study Sponsor:

ST Engineering Innosparks Pte. Ltd.

Purpose of the study

This study is carried out to evaluate the physiological impact of AIR+ KN95 Masks on end-tidal carbon dioxide (ETCO2) of children aged 7 to 14 years of age. The AIR+ KN95 Mask was developed specifically for school-going children. This study is designed to explore whether the new mask is safe and effective for use in healthy children aged 7 to 14 years of age. You may refer to the figure at the end of this Information Sheet for the mask model that your child / ward will be asked to wear (**Appendix A**).

Your child / ward is invited to participate in a research study because your child / ward is a healthy child aged 7 to 14 years old. Before you decide to allow your child / ward to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. A member of the team can be contacted if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish for your child / ward to take part.

This study, conducted over a period of 1 year, will involve 100 students from schools selected by the Ministry of Education (MOE). All students aged 7 to 14 years old studying in these schools will be invited to participate in the study as long as they have no known heart or lung conditions; no known medical conditions that may be worsened by strenuous activity (e.g. exercise-induced asthma) or that may affect exercise capacity; obesity; no recent lower respiratory infection (e.g. pneumonia, bronchitis) in the last two weeks; no recent upper respiratory infection (sore throat, minor cough, fever); no known physical disability from medical disorders of the bones, muscles and nerves; no anxiety disorders; no diabetes; no hypertension; no epilepsy/ seizure disorder; and no acute respiratory infection (e.g. no fever, running nose, sore throat or blocked nasal passages) on the day of study. As your child / ward is currently enrolled in one of these schools, we are approaching him / her for potential participation.

Does your child / ward have to participate? Are there alternatives to participation?

Taking part in this study is entirely voluntary. As such, the decision to participate in this research is completely up to you and your child/ward. You can also withdraw your child / ward from the study at any point without giving any reasons by informing the Principal Investigator.

Your decision for your child / ward not to participate in this study, or to withdraw from this study, will not affect any performance evaluation, medical care or benefits that you or the child may otherwise be entitled to. Refusal to participate will involve no penalty or loss of benefits to which your child / ward is otherwise entitled. No expense is expected from participating in this study.

In the event that your child / ward withdraws midway through the study, any data that may have been collected until that point will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study. Your child / ward can discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled; withdrawal will not affect performance evaluation of your child / ward.

In the event of any new information becoming available that may be relevant to your willingness to allow your child / ward to continue in this study, you will be informed in a timely manner by the Principal Investigator or his representative.

Anticipated circumstances under which your child's / ward's participation may be terminated by the researcher without regard to their consent or the legally authorized representative's consent.

• Failure to follow the instructions of the Principal Investigator and/or study staff.

• The Principal Investigator decides that continuing your participation could be harmful to your health or safety.

• The study is cancelled.

What will happen if my child / ward participates in the study?

If you decide to allow your child / ward to participate in the study, you will need to give consent and complete the parental screening form. Your child / ward will give his/her assent, complete the on-site screening questionnaire and complete the procedures as requested by

the study team (as detailed below). Your child / ward must satisfy the inclusion and exclusion criteria to be an eligible subject.

On the designated study day, we will obtain data on your child/ward's gender, age, height, and weight. They will then undergo a mask fit test to determine the right mask size for their face, and test for leakage by performing the following exercises in sequence, which would take 12 minutes each: normal breathing, deep breathing, turning their heads sideways. If your child/ward is unable to be fitted with any of the mask sizes, they will be excluded from the study.

If your child/ward passes the mask fit test, he/she will don the monitoring equipment and athletic wear. The equipment will monitor breathing rate and heart rate (SPO2) through a Pulse Oximeter **(Figure 1A)** that the child will wear. Carbon dioxide (CO2) concentrations (**Figure 1B**) will also be monitored through a Capnograph with a tube that is clipped onto the earlobe.

Your child / ward will then be assigned a particular sequence of tests; physiological measurements will be assessed while at rest and on mild exertion. Your child / ward will undergo brisk walking on a treadmill with and without wearing the mask (7 minutes each) (**Figure 1C**) and read a book with and without wearing the mask (5 minutes each). Parameters obtained will be recorded in an anonymised case report form.

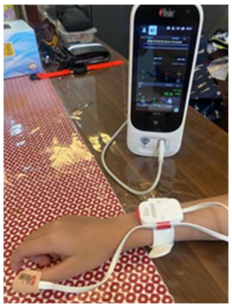


Figure 1A. Pulse Oximeter measure SPO2

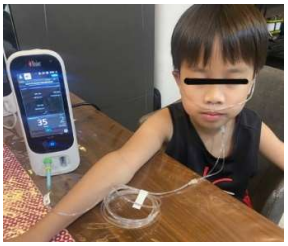


Figure 1B. Capnograph measure of CO2.

Figure 1C. Treadmill Walking intervention.

The general well-being and comfort level of your child/ward whilst wearing the mask will be self-rated using a visual analogue scale (VAS) at the end of the study period. The VAS (**Figure 1D**) is a scale used to determine the pain intensity experienced by individuals. It consists of a line, approximately 10-15 cm in length, with the left side signifying no pain with a smiling face image and the right side signifying the worst pain ever with a frowning face image.

Your child/ward will be asked to point to or mark a spot on the line where they feel indicates their current level of pain. The distance between no pain and the mark made by them creates the pain level. Individual pain tolerance levels can affect the outcome of a VAS.

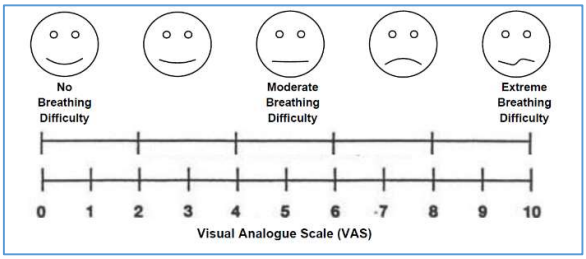


Figure 1D. Visual Analogie Scale (VAS).

Overall, the study should take approximately 1 hour, and will be completed within the same day. No follow-up or repeat study visits are required.

There may be video/ photo recordings of the process of the study for documentation purposes. If the video/ photo recordings are published, no identifiable features of your child/ward will be shown.

You may also refer to the study design (**Appendix B**) at the end of this form.

What is not standard care or experimental in this study

The on-site screening questionnaire, face mask fitting, and measurements of the physiological parameters (heart rate, breathing, oxygen saturation and ETCO2) are not part of your standard care (e.g., a routine health check) but these will help doctors and others in the community to ascertain the safety and effectiveness of the AIR+ KN95 Mask.

Will any biological samples (e.g., blood/ urine) be taken?

There will not be any invasive procedures (i.e., we will not be subjecting your child/ward to any needles or medications), nor do we need to collect any urine or blood samples from them.

Incidental Findings

There will not be any incidental findings (defined as findings that have potential health or reproductive importance to research participants, and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study) arising from this research.

Eligibility Criteria

- Your child/ward must be aged between 7 and 14 years of age (inclusive)
- You must consent/ assent your child/ward to take part in this study
- Your child/ward should not have a history of any known cardiorespiratory conditions (including but not limited to the following: asthma, bronchitis, cystic fibrosis, congenital heart disease, emphysema)
- Your child/ward should not have a history of any known medical conditions that may be exacerbated by strenuous activity, including but not limited to the following: exercise-induced asthma, lower respiratory infection (including pneumonia, bronchitis) in the past 2 weeks, anxiety disorders, diabetes, hypertension, or epilepsy/ seizure disorder

- Your child/ward should not have any physical disability from medical, orthopaedic or neuromuscular disorders
- Your child/ward should not have an acute upper respiratory tract infection/ moderately severe rhinitis (i.e., blocked nasal passages) on the day of the study
- Your child/ward should not have features that may compromise the integrity of the mask fit (e.g., those with excessive facial hair)

Are there possible disadvantages and/or risks and/or side effects from participating?

No severe risks or side effects are anticipated in this study. Overall, the study is designed to observe the impact of wearing the AIR+ KN95 Mask in children while at rest and on minimal physical exertion only. They may experience mild discomfort when wearing the mask whilst brisk walking on the treadmill. However, their vital signs will be monitored, and they will be encouraged to remove the mask if they feel uncomfortable. Studies have shown that prolonged wearing of disposable particulate respirators may lead to an increase in carbon dioxide (CO_2) levels which may result in headaches, increased irritability, or breathing discomfort. This is typically resolved by simply removing the mask.

What are the possible benefits to my child and to others?

There is no direct benefit to your child / ward in participating in this research. The knowledge gained would benefit other children and the public in the future. The results from this research will enable us to test the safety of the use of Air+ KN95 masks in children. The safety issue studied here is in the context of concerns over the carbon dioxide build-up that can occur inside the mask as a person exhale (breathes out). Usually, this is resolved by simply removing the mask. This study will measure the carbon dioxide levels inside the mask and in the children as they wear it.

Token of appreciation for participation

All students who participate in and complete the study will be provided with a complimentary set of AIR+ KN95 Masks, and a $30 book voucher as a token of their participation at the end of the study visit.

How will my child/ward's privacy and confidentiality of the research records be protected?

Your child's / ward's identifiers will be removed from the data collected. All forms will be coded at source. The data will be stored in a stand-alone computer that will be password-protected and stored in a secure location within the Principal Investigator's office premises.

Information collected for this study will be kept confidential. Your records, as well as the records of your child / ward, to the extent of the applicable laws and regulations, will not be made publicly available.

However, Parkway Independent Ethics Committee (PIEC) and Ministry of Health will be granted direct access to Child/Ward's Medical History in Parental Screening Form to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you are authorizing (i) collection, access to, use and storage of you and your child/ward's "Personal Data", and (ii) disclosure to authorised service providers and relevant third parties.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organization has or likely to have access. This includes medical conditions, medications, investigations, and treatment history. By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at https://www.stengg.com/st-engineering-personal-data-policy.

Research arising in the future, based on this Personal Data, will be subject to review by the relevant institutional review board.

What will happen to the results of the research project?

Manuscripts discussing the study results may be submitted to scientific journals for publication consideration in the future; such manuscripts will only contain de-identified data.

What is the compensation for any injury?

If your child / ward follows the directions of the investigators in charge of this study and he/she is physically injured due to the trial procedure given under the plan for this study, ST Engineering Innosparks Pte. Ltd. will pay the medical expenses for the treatment of that injury.

ST Engineering Innosparks Pte. Ltd. without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove ST Engineering Innosparks Pte. Ltd. is at fault.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

Who is organising and funding the research?

This study is funded by ST Engineering Innosparks Pte. Ltd.

Ethical review of the study

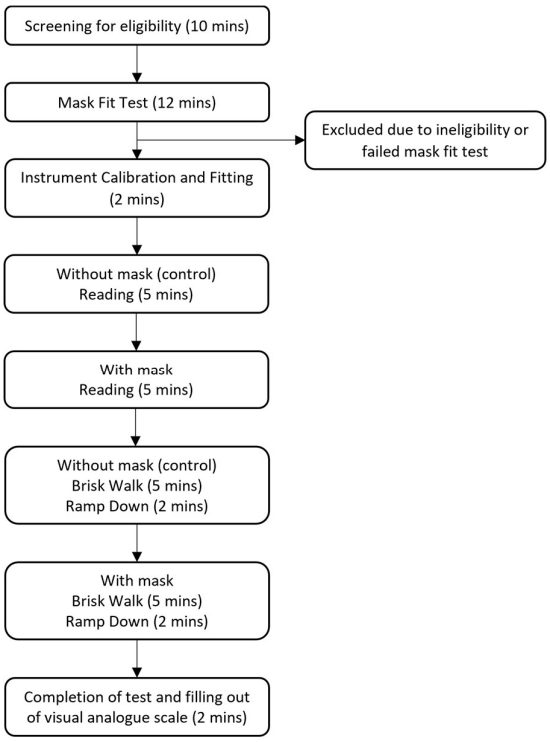
This study has been reviewed by the Parkway Independent Ethics Committee (PIEC).

Contact for further information The Principal Investigator and Co-Investigator, Mr Jerome Lee Wei Liang, are salaried staff employed by ST Engineering Innosparks Pte. Ltd., whose product (Air+ KN95 mask) is being investigated in this study.

Appendix A. AIR+ KN95 Mask Model

AIR+ KN95 mask

Appendix B. Study Design



CONSENT FORM

Study Title:

A study to explore the physiological impact of AIR+ KN95 Masks on children

Principal Investigator:

Eugene Loy
Business Development Manager
Respiratory Protection
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Singapore 528553
Contact No: (+65) 6873 2074

Study Sponsor:

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I voluntarily consent for my child / ward, _____(last 4 digits of NRIC/FIN No.), to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction.

By consenting to my child / ward participating in this research study, I confirm that I have read, understood and consent to ST Engineering Innosparks Pte. Ltd. Personal Data Protection Notification.

I hereby acknowledge that:

- My signature is my acknowledgement that I have agreed to allow my child / ward to take part in the above research.
- I have read and understand the eligible criteria and that my child / ward is eligible to participate at the time of acknowledgement and he/she will undergo an onsite pre-test screening to check on he/her current onsite well-being before study commences.
- My child / ward can choose to withdraw from the research at any point of time by informing the Principal Investigator or study team.
- I will not have any financial benefits that result from the commercial development of this research.
- My child's / ward's personal identifiers (name, last 4 digits of NRIC) will not be disclosed in any publication or presentation relating to this research.

- Any video or photograph of my child / ward taken during the research study, if subsequently published, will not contain any identifiable features of my child / ward.

Please detach and return signed copy to school

I also **consent/ do not consent*** to the use of my child/ward's Personal Data (no identifiable features will be mentioned) for the purposes of engaging in related research arising in the future.

I also **agree/ disagree*** to allow the study team to

1) Store my child / ward's data for any future research.
2) Contact me directly for verification of information if in doubt

_____	_____	_____
Name of Subject (>12 years)	Signature	Date

_____	_____	_____
Name of Parent or Legal Guardian	Signature	Date

Please detach and return signed copy to school

To be completed by Witness

☐ I, the undersigned, am 21 years of age or older and have ascertained the identity of the child/ward and certify to the best of my knowledge that the information in the consent document and any other written information was accurately explained to my child/ward in a language understandable by my child/ward, and the informed consent was given voluntarily by my child/ward without any coercion or intimidation.

In the event the child/ward* or the parent/legal guardian is unable to read

☐ I declared that I am independent of the research study mentioned above and I am not unfairly influenced by anyone involved in the research.

Name of Witness	Relationship with Research Subject / Designation	Contact

Signature	Date

Site Investigator Statement

I, the undersigned, certify that I explained the study to the child / ward* and to the best of my knowledge the child / ward* clearly understands the nature, risks and benefits of his/her participation in the study.

Name of Site Investigator administering consent	Signature	Date

** Delete accordingly*

Please detach and return signed copy to school

Parental Screening Form of Child / Ward's Medical History

Study Title: A study to explore the physiological impact of AIR+ KN95 Masks on children

Principal Investigator:

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Contact No: (+65) 6873 2074

Please tick yes or no to the questions below

	Questions to be asked	Yes	No
1.	Is your child/ward aged between 7 and 14 years of age (inclusive)		
2.	Have you and your child/ward given consent or assent to take part in this study?		
3.	Does your child/ward have any known cardiorespiratory conditions (including but not limited to the following: asthma, bronchitis, cystic fibrosis, congenital heart disease, emphysema)		
4.	Does your child/ward have any known medical conditions that may be exacerbated by strenuous activity, including but not limited to the following: exercise-induced asthma, lower respiratory infection (including pneumonia, bronchitis) in the past 2 weeks, anxiety disorders, diabetes, hypertension, or epilepsy/ seizure disorder?		
5.	Does your child/ward have any physical disability from medical, orthopedic, or neuromuscular disorders?		

Remark: Please list any medical condition(s) that your child may have which are not mentioned above.

_____
_____

_____ _____ _____
Name of Parent or Legal Guardian Signature Date

_____
Contact Number or Email**

** For study team to contact the parent/legal guardian directly for verification of the above information if in doubt, prior to the enrolment of the subject in the study. Any such correspondence will be documented in the study record.

Please detach and return signed copy to school