Effect of vehicle vibration on healthy term infants: Method and infant car seat vibration quantification

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Abstract

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Even though infants are frequent vehicle travellers, little is known about the effect of vibrations on their comfort and health. Some studies have characterised the vibrational response of infant car seats, while others have focussed on the physiological responses of infants secured in infant car seats under varying operating conditions (stationary, vertically simulated or varying infant postures). The void identified in the current literature is - the relationship between in-vehicle multi-axis vibration input to a new-born infant seated in an infant car seat, and the resulting changes in posture and cardiorespiratory response of the infant. This study aims to form a basis for future studies seeking to investigate the effect of vehicle vibration on healthy, term infants by establishing a comprehensive method and investigating the multi-axis transmissibility of the infant car seat and subsequent vibration input that infants may experience during testing. The relationship between the responses of infants to vehicle vibration and the vibration frequencies, -magnitudes or -directions can be used to design infant car seats that not only provide protection in the event of a crash, but also promote the health of the infant under normal driving conditions.

A comprehensive method was developed for an investigation into the effect of vehicle vibrations on new-born infants. Aspects addressed in this method include quantifying the vibration input to the infant, tracking the infant’s change in posture and measuring their cardiorespiratory response.

As the proposed method relies on in-field testing, the road inputs and speed of the vehicle have been identified as aspects that may influence the vibration input to infants. The mission

profile was selected such that it includes road inputs typically found during suburban driving. The vehicle speed was found to have a statistically significant ($p < 0.05$) influence on the vibrational response of the vehicle body, and based on available difference thresholds, will be perceptible by adult occupants. Whether these differences will result in different responses between infants remains to be investigated. The transmissibility of the infant car seat was determined over the selected mission profile. Although frequencies could be identified where the infant car seat amplified the vibration input to infants, the coherencies determined for the in-vehicle measurements made it challenging to interpret the transfer functions obtained.

If the findings presented in this study are considered during investigations into the response of infants to vehicle vibration, a holistic approach will be followed which considers many of the aspects that may influence the observed responses. This should provide meaningful insight into the effect of vehicle vibration on the health of infants under normal driving conditions, as this effect has not been investigated before.

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List of Symbols

Symbol	Description	Units
$\gamma^2_{k,io}$	Ordinary Coherence function	-
$\|H(f)\|$	Modulus of complex transfer function $H_k(f)$	-
$A_{0,k}$	Acceleration measured by accelerometer 0 (k = x, y and z directions)	m/s^2
$A_{1,k}$	Acceleration measured by accelerometer 1 (k = x, y and z directions)	m/s^2
$A_{2,k}$	Acceleration measured by accelerometer 2 (k = x, y and z directions)	m/s^2
$A_{3,k}$	Acceleration measured by accelerometer 3 (k = x, y and z directions)	m/s^2
$A_{cs,i}$	Car seat base accelerometer, i = 0 to 2	-
$A_k(i)$	Sampled acceleration values in direction k	m/s^2
$A_{rms,k}$	RMS acceleration measured in the direction k	m/s^2
$A_{v,\,i}$	Vehicle accelerometer, i = 0 to 3	-
D_x	Distance between accelerometer 0 and accelerometer 2	m
d_x	Distance in x-direction between accelerometer 0 and arbitrary point P	m
D_y	Distance between accelerometer 0 and accelerometer 1	m
d_y	Distance in y-direction between accelerometer 0 and arbitrary point P	m
D_z	Distance between accelerometer 0 and accelerometer 3	m
d_z	Distance in z-direction between accelerometer 0 and arbitrary point P	m
$G_{k,ii}(f)$	Power Spectral density of input, k = x, y or z direction	$(m/s^2)/Hz$
$G_{k,io}(f)$	Cross spectral density between input and output, k = x, y, z direction	$(m/s^2)/Hz$
$G_{k,oo}(f)$	Power spectral density of output, k = x, y, z direction	$(m/s^2)/Hz$
$H_k(f)$	Complex seat transfer function	-
N	Number of sampled acceleration values	-
r_x	Roll	rad/s^2
r_y	Pitch	rad/s^2
r_z	Yaw	rad/s^2

T_s	Vibration duration	s
$\varphi(f)$	Phase of Complex transfer function Hk(f)	°
φs	Angular displacement of the infant head in the sagittal plane from the reference position	°

List of Abbreviations

Abbreviation	Description
AAP	American Academy of Paediatrics
APGAR	Appearance, Pulse, Grimace, Activity, and Respiration
BPM	Beats Per Minute
BS	British Standard
CF	Crest Factor
DC	Direct Current
EBIT	Engineering, Built Environment and Information Technology
GPS	Global Positioning System
HR	Heart Rate
ICS	Infant Car Seat
ICSC	Infant Car Seat Challenge
Im	Imaginary
IMU	Inertial Measurement Unit
IP	Ingress Protection
IQR	Inter Quartile Range
ISO	International Organization for Standardization
MI-SO	Multiple-Input, Single-Output
NCAP	New Car Assessment Program
NICU	Neonatal Intensive Care Unit
POI	Point Of Interest
PSD	Power Spectral Density
Re	Real
REC	Research Ethics Committee
REM	Rapid Eye Movement
RMS	Root Mean Square
RR	Respiratory Rate
SANS	South African National Standard
SIDS	Sudden Infant Death Syndrome

SI-SO	Single-Input,Single-Output
SpO_2	Oxygen saturation levels
UP	University of Pretoria
VDG	Vehicle Dynamics Group
VDV	Vibration Dose Values
VS	Vehicle Seat
WBV	Whole-Body Vibration

List of Definitions

Engineering Definitions

Term	Definition
Absorbed Power	The power dissipated in a mechanical system as a result of an applied force
Biomechanical	Relating to the mechanical laws concerning the movement or structure of living organisms
Pitch	A swaying or oscillation of a ship, aircraft, or vehicle around a horizontal axis perpendicular to the direction of motion
Resonance	The condition in which an object or system is subjected to an oscillating force having a frequency close to its own natural frequency
Roll	Rock or oscillate round an axis parallel to the direction of motion (of a moving ship, aircraft, or vehicle)
Sprung mass	Portion of the vehicle's total mass that is supported above the suspension
Transmissibility	Ratio of output to input
Yaw	Twist or oscillate about a vertical axis (of a moving ship or aircraft)

Medical Definitions

Term	Definition
Apnoea	Temporary cessation of breathing, especially during sleep
Bradycardia	Abnormally slow heart action
Cardiorespiratory	Relating to the action of both heart and lungs
Congenital anomalies	Birth defects, congenital disorders or congenital malformations

Coronal plane	A vertical plane at right angles to a sagittal plane, dividing the body into anterior and posterior portions
Gestational age	Used to describe how far along a pregnancy is. It is measured in weeks, from the first day of the woman's last menstrual cycle to the date of birth of the infant
Hypotonia	An abnormally low level of muscle tone
Inter-subject variability	Variability occurring between subjects in an experiment
Intra-subject variability	Variability occurring between the same subject at different occasions
Ischial tuberosities	Known informally as the sit bones, the ischial tuberosity is a rounded bone that extends from the ischium — the curved bone that makes up the bottom of your pelvis
Neonatal	Relating to newborn children (or other mammals)
Occiput	The back of the head
Oxygen desaturation	A decrease in oxygen concentration in the blood resulting from any condition that affects the exchange of carbon dioxide and oxygen
Oxygenation	The addition of oxygen to any system, including the human body
Postnatal	Relating to or denoting the period after childbirth
Prenatal	Before birth; during or relating to pregnancy
Pulse oximeter	An oximeter that measures the proportion of oxygenated haemoglobin in the blood in pulsating vessels, especially the capillaries of the finger or ear
Sagittal plane	Of or in a plane parallel to the sagittal suture, especially that dividing the body into left and right halves
Supine	Lying face upwards (of a person)

Definitions obtained from English Oxford Living dictionaries (Oxford, 2018) and Farlex (2018)

Chapter 1: Introduction

The field of human response to vibration considers the impact of vibration on the health, comfort and activities of humans, where these evaluations can be performed within a vehicle environment. Investigations have been performed to determine the subjective comfort levels of adult occupants being exposed to different levels of whole-body vibration. Investigations concerning the effect of vibration on comfort have been based upon participants supplying some form of subjective feedback on the levels of comfort that they are experiencing. The short-term impact of vehicle vibration on the health of occupants can be assessed based upon the physiological response of an occupant who is exposed to vehicle vibration (Griffin, 1990).

In the absence of subjective feedback, as is the case of infants being exposed to vibration, the only option is to measure their physiological response. These measurements may then serve as an indication of the short-term health impact of vibration on the infant. A limited body of knowledge is available that addresses an infant's response to whole-body vibration, including being seated in an infant car seat during vehicle travel. This lack of information is a relevant problem, as all infants who are born in a hospital or clinic must, upon discharge, be transported home by some means. The American Academy of Pediatrics (AAP) has observed a correlation between negative cardiorespiratory responses in preterm infants and being seated in an infant car seat. The AAP has thus recommended that all preterm infants complete an 'infant car seat challenge' before being discharged from hospital (American Academy of Pediatrics, 1999). This static challenge may however not be representative of the response of infants in a moving vehicle.

As part of the investigation of the response of an infant to vehicle vibration it is important to quantify the vibration to which the infant is exposed and understand the role of the infant car seat in the transfer of vibration from the vehicle to the infant. If the response of an infant subjected to multi-axis vehicle vibration can be linked to a specific vibration direction, frequency and/or magnitude, this information can be useful in the design of infant car seats that not only provide crash protection, but also enhance the health of infants during normal driving conditions.

Chapter 2 will proceed to give a thorough summary of the available literature that assisted in identifying the problem addressed during this study. The problem statement and an overview of the study is presented in Chapter 3 to provide context to the investigations conducted. Chapter 4 documents the comprehensive method developed for a study investigating the response of infants to whole-body vibration. The vibration input to an infant, including the factors that may influence this vibration input is described in Chapter 5. The multi-axis transmissibility of the infant car seat under real driving conditions is investigated in Chapter 6. The main conclusions from the research are presented in Chapter 7, while recommendations for future work are presented in Chapter 8.

Chapter 2: Literature Study

This section serves to logically document the process that was followed to investigate current literature and identify voids. The voids identified from literature are then used to formulate the problem statement presented in Chapter 3. Human response to vibration, specifically the response of infants to vehicle vibration, is the field of interest.

2.1 Human Response to Vibration within a Vehicle Environment

Human response to vibration is a wide field applicable to different industries, including the automotive industry. During vehicle travel, road inputs are transferred to the vehicle body through the suspension components. The resulting vibration is then transferred to the occupant through the points of contact between the occupant and the vibrating vehicle environment, which includes the seat, the vehicle floor and, in the case of the driver, the steering wheel. The vibration transferred to the occupant will influence the occupant in a complex way, and each occupant's response will vary for different measurement instances (intra-subject variability) and from the responses of other occupants (inter-subject variability).

2.1.1 Human Response to Vibration

Human response to vibration can be evaluated based upon its effect on comfort, interference with activities and impairment of health. Numerous factors have been identified that influence the response of a person to whole-body vibration (WBV) exposure. The most obvious factors are related to the vibration characteristics such as magnitude, frequency and the duration of vibration exposure. Certain confounding factors have also been identified, namely environmental conditions (such as noise, lighting and temperature), the activities of the person (such as sitting, lying or driving), subjective assessments (for example drawing comparisons between current and past experiences) as well as the characteristics of the person (such as body dimensions and body mass, age and posture) (Griffin, 1990).

The responses to vibration exposure may be obtained in the form of subjective feedback of the participant, or objective measurements of changes in the participant's physiological state. Due to the complexity of human response to vibration, a multi-disciplinary approach is taken to understand the effect of each of the factors on the observed response. Individuals within the field of engineering can analyse the vibrational characteristics, while physiological responses can be analysed by specialists in the fields of medicine or physiology. Psychologists can also assist in understanding the subjective responses of participants.

Each of the influencing factors contribute to an individual's response in a unique way, as each individual is also subject to inter- and intra-subject variability. A perfect model that can describe the response of all persons most likely does not exist. Statistics are, however, used to describe the possible response of a person within a population. This is based upon the distribution of responses displayed by a sample of participants, which is representative of the population. Many of the prominent findings from studies investigating the effect of human response to WBV have been used to establish standards for the measurement and evaluation of human exposure to WBV, such as BS 6841 (1987) and ISO 2631-1 (1997).

2.1.2 Application of Human Response to Vibration within a Vehicle Environment

During vehicle travel, vehicle occupants are exposed to WBV, which influences the comfort, health and activities of the occupant. Although standards such as BS 6841 (1987) and ISO 2631-1 (1997) have been developed for the evaluation of human exposure to WBV, new research is performed on a regular basis to evaluate the effect of vehicle vibration on the health and comfort of vehicle occupants. This information is used to develop systems within the vehicle (for example vehicle seats and suspension components) together with further development of the standards and regulations pertaining to human response to vibration.

Several investigations have sought to answer important questions regarding WBV and the comfort experienced by vehicle occupants. Most of these studies investigated the effect of vibration magnitude (Morioka and Griffin, 2006) or vibration frequency (Griffin, 2007) in a specific vibration direction (translational or rotational) for a seated person. Some investigations have also been performed to evaluate the discomfort associated with multiple-axis vibration (Dickey et al., 2007). Many of these investigations are based upon some form of subjective feedback obtained from participants being exposed to various levels of vibration. The results of selected investigations that included subjective participant feedback have been compiled into what is known as the frequency weightings of human vibrational exposure (BS 6841, 1987, ISO 2631-1, 1997).

Mansfield and Griffin (2000) determined the difference threshold for adults in the vertical direction, which is the smallest change in a stimulus that can be detected. A study performed by Gräbe (2017) investigated the ride comfort difference thresholds of a vehicle on a 4-poster with adult participants subjected to multi-axis (translational and rotational) vibration input. A 75th percentile relative difference threshold (where 75% of test participants will have a 79.4% probability of identifying the larger of two stimuli) of 13.18% was reported for BS 6841 (1987) weighted vertical seat vibration for a smooth road input.

The effect of vehicle vibration on occupant discomfort is, however, not the only concern, and the question whether vehicle vibration exposure has a negative impact on the health of occupants is certainly another important issue. Due to the complexity of human response to vibration within an actual vehicle environment, it is challenging to determine a direct cause-effect relationship between vibration exposure and long-term effects such as the development of disease. The temporary effect may, however, be observed as a change in the normal physiological response of a person exposed to vibration (Griffin, 1990). The responses to vibration may either be positive or negative. Vibration exposure may either enhance the functioning of systems within the human body (such as increased blood circulation) or decrease its efficiency (such as deteriorating vision at certain vibration frequencies). Recent studies have confirmed a correlation between cardiorespiratory response (oxygen uptake and heart rate) and WBV exposure (Gojanovic et al., 2014). A recent study by Jooste (2018) has found that, exposing participants to different vertical vibration levels exceeding the relative difference threshold of 13%, results in no change of the observed cardiovascular response. It would, however, be ideal if the subjective feedback from test participants can be correlated with objective physiological measurements.

Although many questions still exist regarding human response to vibration within the vehicle environment, most studies have sought to answer these questions for adult occupants. Children and infants are, however, regular vehicle occupants. Most infants who are born in a hospital must, upon discharge, be transported home by some means, whether it be by private or public transport. There is thus a need to determine the effect of this vibration exposure on these occupants who are not merely scaled versions of adults.

The in-vehicle acceleration measurements of a study performed by Giacomin and Gallo (2003) suggested that the WBV resonance frequencies of infants were different compared to those of adults. While it is known that the principal WBV resonance frequency of seated adults is approximately 5Hz (Kitazaki and Griffin, 1998), Giacomin and Gallo's study indicated that infants display resonance at a frequency of 8.5Hz. This can be expected due to the significant differences in body mass distribution and body composition (Giacomin and Gallo, 2003). A subsequent study performed by Giacomin (2005) indicated that the vertical whole-body power absorption properties of small children are different compared to those of adults. The results from the laboratory tests indicated a mean frequency peak absorption of 7.4Hz for small children, compared to 4.0 - 5.0Hz for adults. This demonstrates that, in addition to the differences in WBV resonance frequencies, the manner in which vibration is absorbed differs between small children and adults. The applicability of the analysis methods and frequency weightings that have been developed for adult vehicle occupants to children and infants, especially new-born infants, therefore need to be investigated.

2.2 Cardiorespiratory Response of Infants Seated in an Infant Car Seat

This section discusses the infant car seat challenge that has been recommended by the American Academy of Pediatrics (AAP). It also considers the cardiorespiratory response of infants in stationary infant car seats and seats subjected to vibration.

2.2.1 Infant Car Seat Challenge

The AAP recommends that all preterm infants be observed in their infant car seats (commonly known as the Infant Car Seat Challenge or ICSC) before being discharged from hospital (American Academy of Pediatrics, 1999). This recommendation is based upon the increased number of events of oxygen desaturation, apnoea and bradycardia that have been observed for preterm infants that are seated in infant car seats. Failing the ICSC results in the infant remaining in hospital for further observation or having to make use of a car bed for transportation (depending on whether the infant's response was stable when tested in a car bed). This will prevent an infant with immature cardiorespiratory systems from being exposed to a situation that may compromise their health.

A recent study by Davis et al. (2013) identified that discrepancies exist between the implementation of the recommendations by the AAP, as the suggested testing time varies from 90 to 120 minutes. The lack of a universal definition of failure criteria for the ICSC is also problematic. It was therefore suggested that all infants born before a gestational age of 37 weeks need to complete the ICSC. The ICSC would need to be performed for 90 minutes, where a bradycardia of less than 80 bpm for more than 10s, and oxygen saturation levels (SpO_2) less than 90% for more than 10s will be used as failure criteria.

2.2.2 Stationary Infant Car Seat

A study by Merchant et al. (2001) showed that term and preterm infants display a negative cardiorespiratory response while seated in a stationary infant car seat, i.e. placed on a hard surface in the hospital at the inclination angle prescribed by the infant car seat manufacturers and not within a moving vehicle. There was no significant difference between the SpO_2 of preterm and term infants. The mean SpO_2 decreased from 97% (92%-100%) in the supine position to a mean of 94% (87%-100%) after 60 minutes in the seated position. It is not common to see SpO_2 lower than 90% in healthy infants, which suggests that the upright position of the infant car seat leads to suboptimal oxygenation. The responses also included oxygen desaturation and events of apnoea and bradycardia, where 12% of preterm infants displayed apnoeic or bradycardic events. Tonkin et al. (2003) showed that a simple infant car seat insert reduces the number of oxygen desaturations and events of bradycardia displayed by preterm infants secured in a stationary seat. This has been linked to the posture of the infant, as the upright position together with the prominent occiput of a new-born infant (specifically preterm infants), results in flexion of the head which restricts the airway. This head flexion was identified as a significant contributor to the episodes of oxygen desaturation and bradycardia observed. The use of the infant car seat insert resulted in an increase in the size of the upper airway, from a mean of 3.6mm without the insert to a mean of 5.2mm with the insert in place.

2.2.3 Infant Car Seat with Smooth Road Input

Up until recently, the cardiorespiratory response of infants seated in infant car seats have only been determined in stationary conditions. A pilot study performed by Arya et al. (2017) was the first to investigate the effect of motion on the cardiorespiratory response of infants.

The cardiorespiratory response, namely SpO_2, respiratory rate (RR) and heart rate (HR), of preterm and term infants were measured throughout four different tests. These tests included baseline measurements while the infant was lying in a cot in the supine position; while seated in a stationary infant car seat at two different inclination angles; and while being exposed to motion. During this study, an infant car seat was mounted on a motion simulator that reproduced the vertical vibration experienced at the base of an infant car seat located within a vehicle travelling over a smooth road at a speed of approximately 48km/h. The results indicated that a higher prevalence of oxygen desaturation was present in infant car seats that had a larger inclination angle, and that the addition of vertical motion increased the number of desaturations even further, regardless of the gestational age of the infant.

2.2.4 Cardiorespiratory Response Measures Investigated

A summary of the cardiorespiratory measures investigated thus far can be seen in Table 1. The criteria that warranted the termination of tests for the protection of the infants is also summarised in Table 1. This summary will be used later in section 0 as a guideline in deciding which parameters will need to be included in the study, and how the definition of noteworthy response events will be formulated.

Table 1: Summary of cardiorespiratory responses investigated in past studies

Study	Continuous cardiorespiratory measurements			Definition of noteworthy response events			Criteria for termination of tests
	SpO_2	HR	RR	Oxygen desaturation	Apnoea	Bradycardia	
Merchant et al. (2001)	✓	✓	✓	SpO_2< 85%	Respiratory pause > 20s	HR < 80bpm	HR<80bpm for >4s with SpO_2<80% HR<80bpm > 10s Respiratory pause > 20s with SpO_2<80% or HR < 80bpm SpO_2<80% for > 10s
Tonkin et al. (2003)	✓	✓	✓	SpO_2< 85%	Reduced air flow and increased respiratory effort	HR < 90bpm	Persistent oxygen desaturations
Arya et al.	✓	✓	✓	↓ SpO_2 > 4% for > 10s or SpO2 < 85% for > 4s	Respiratory pause > 10s	HR < 100bpm for preterm and HR < 60bpm for term	SpO_2 < 85% for > 20s Respiratory pause > 15s
Davis et al. (2013)	✓	✓	x	-	-	-	HR < 80bpm for > 10s SpO_2 < 90% for > 10s

2.3 Vibration Input to Infants

In understanding the response of an infant travelling in a vehicle, it is important to consider the vibration that the infant is exposed to. The vertical transfer of vibration in a typical vehicle travelling in the longitudinal direction can be seen in the simple quarter car model depicted in Figure 1. The tyre is in contact with the road, where undulations and distinct objects in the road provide a certain input to the tyre. The tyre has damping and stiffness characteristics that influence the vibration transfer to the un-sprung mass, which consists of the suspension components and wheels. The suspension then transfers vibration to the sprung mass or vehicle body, which in turn transfers the vibration to the seat within the vehicle. In most cases, it is assumed that the connection between the seat and vehicle body is rigid and thus has a very high stiffness and damping coefficient. Vibration is then transferred from the vehicle seat to the infant car seat, and again from the infant car seat to the infant.

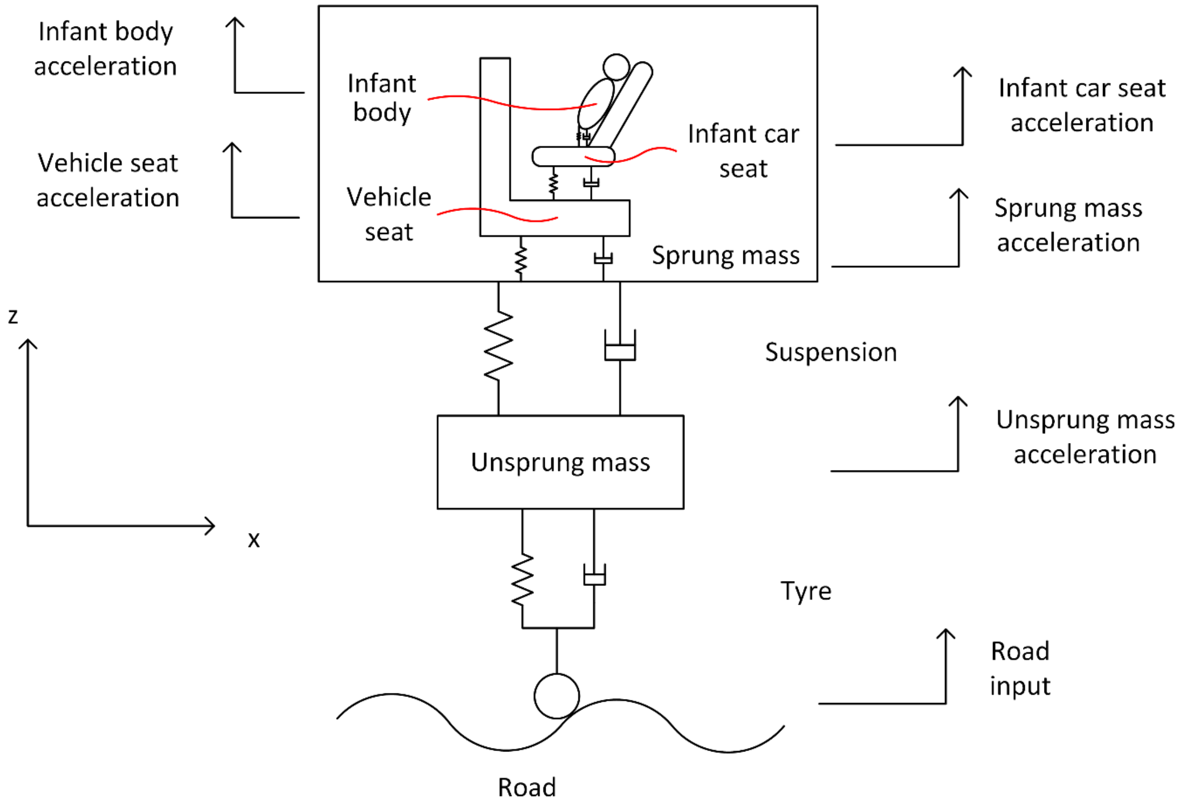

Figure 1: Vibration transfer through a vehicle to an infant

Each mass within this vehicle system displays a unique response, which is dependent on the properties of the springs and dampers to which it is connected. These springs and dampers represent the stiffness and damping properties of the interacting surfaces, which can be presented in the form of a transfer function. This transfer function is a complex, mathematical function of frequency relating the response of each mass contained within this vibrating vehicle environment with the stimulus provided to the mass (Griffin, 1990). The transfer function for the vehicle seat is often of interest in seat design, as designers would aim to have the seat attenuate some of the vibration transferred to the occupant (Griffin, 1990). It is therefore equally important to understand the effect of the infant's car seat and the transfer of vibration, as the dynamic response of the seat can be altered to better isolate the infant from WBV. However, the main design considerations of infant car seats have been with respect to crashworthiness and ergonomics (Automobile Association of South Africa, n.d.). In order to be able to design an infant car seat with the optimal isolating properties, it is necessary to understand how vibration affects the infant.

2.3.1 Vibration Measurement Techniques

When testing human response to vibration within a vehicle environment, vibration is classified in terms of acceleration measurements. These acceleration measurements are obtained from the most relevant interface locations between the human and vehicle. Various techniques have been developed to measure the vibration within a vehicle environment, however the technique discussed in Griffin (1990) will be described in the following section. For this study, the orthogonal coordinate system convention of ISO 2631-1 (1997) is adopted, where vertical motion refers to the z-direction, lateral motion refers to the y-direction and longitudinal motion refers to the x-direction.

Vibrational Response of Vehicle Bodies

The measurement technique discussed in Griffin (1990) employs the use of three linear tri-axial accelerometers to estimate the rotational acceleration of a rigid body, as well as the translational acceleration at any arbitrary point (P) of the rigid body based upon kinematic principles. The accelerometers mounted to the rigid body (A_0, A_1 and A_2) are indicated as black, solid dots in Figure 2, while the arbitrary point (A_p) is indicated as a red, shaded dot.

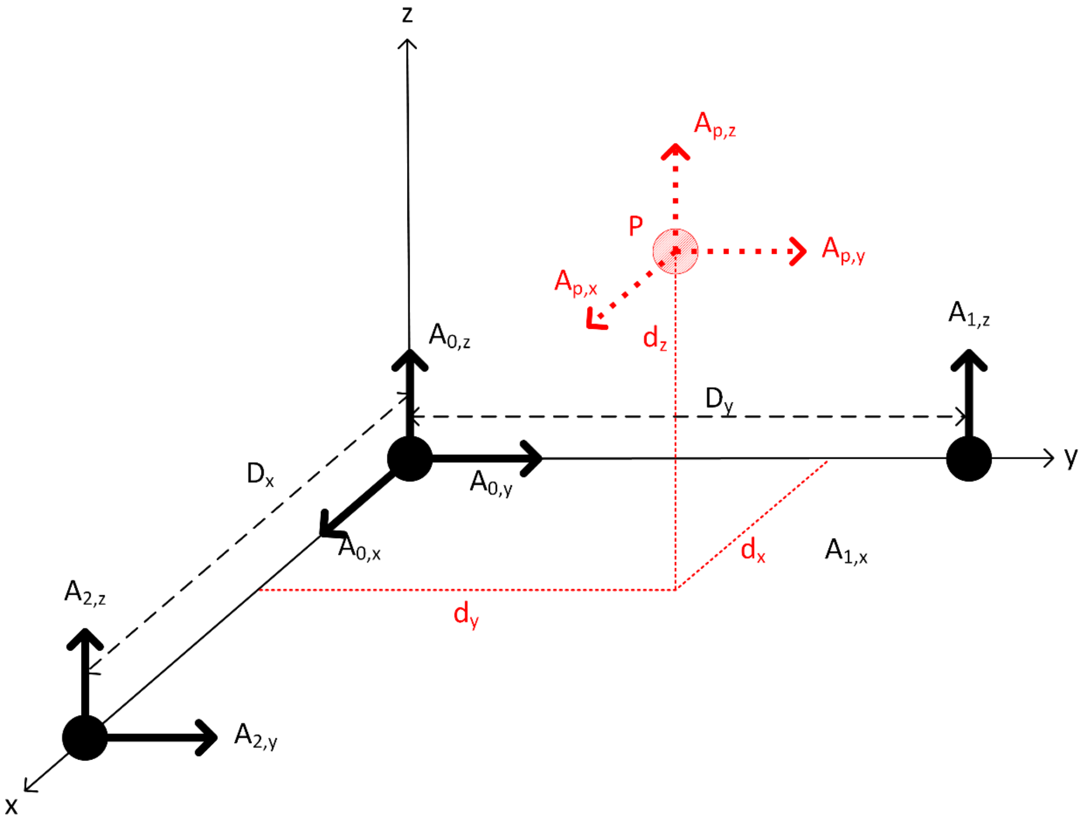

Figure 2: Accelerometer configuration to approximate rotational acceleration of a rigid body and translational acceleration at a point of interest (P) located on the rigid body

Each of the accelerometer measurements will be used to estimate the three rotational acceleration components that the rigid body is experiencing. The rotational acceleration components - roll (r_x), pitch (r_y) and yaw (r_z) - can be approximated using the following relationships given by Griffin (1990),

$$r_x = \frac{A_{1,z} - A_{0,z}}{D_y} \tag{1}$$

$$r_y = \frac{-(A_{2,z} - A_{0,z})}{D_x}[1] \tag{2}$$

$$r_z = \frac{A_{2,y} - A_{0,y}}{D_x} \tag{3}$$

[1] The equation presented here differs from the equation presented in GRIFFIN, M. J. 1990. *Handbook of Human Vibration,* London, Academic Press. A sign error was noted for the convention selected for the estimation of rotational accelerations, and has been corrected for in Equation (2)

The translational acceleration components of an arbitrary point P located on the rigid body can also be approximated using the relationships given below, which were also presented by Griffin (1990),

$$A_{p,x} = A_{0,x} - \frac{A_{2,z} - A_{0,z}}{D_x} \cdot d_z - \frac{A_{2,y} - A_{0,y}}{D_x} \cdot d_y \tag{4}$$

$$A_{p,y} = A_{0,y} + \frac{A_{2,y} - A_{0,y}}{D_x} \cdot d_x - \frac{A_{1,z} - A_{0,z}}{D_y} \cdot d_z \tag{5}$$

$$A_{p,z} = A_{0,z} + \frac{A_{2,z} - A_{0,z}}{D_x} \cdot d_x + \frac{A_{1,z} - A_{0,z}}{D_y} \cdot d_y \tag{6}$$

This technique is typically used to estimate the translational and rotational vibration response of a vehicle body, where the accelerometers are often mounted to seat rails that are rigidly connected to the vehicle floor. Depending on the method used to fasten the accelerometer to the seat rail, it can be assumed that the accelerations measured are representative of the response of the vehicle sprung mass. The errors incurred by making use of this method are small if the rotation about one axis is appreciably smaller than that about other axes (Griffin, 1990). When driving under normal conditions over typical suburban roads, it is expected that the yaw measured within the vehicle would be notably smaller than the roll or pitch, making this technique suitable for this in-vehicle measurements obtained under the specified conditions. The method described here is dependent on the assumption of the rigidity of the body, and therefore does not apply to flexure.

Vibration Input to Infants

The vibration input to vehicle occupants are typically measured through a transducer that is located at the interface between the test participant and the surface providing the vibration input. In the case of infants this vibration input is provided through the infant car seat, which transfers the vibration from the vehicle seat to the infant. Based on the non-linearities observed for the transfer of vibration from vehicle seats to adult vehicle occupants (Tufano and Griffin, 2013), it is anticipated that the materials used to manufacture infant car seats will also result in non-linear transfer of vibration to the infants. The vehicle seat also transfers vibration non-linearly from the vehicle body to the infant car seat. The vibration input to the infant may be measured using a seat pad accelerometer conforming to ISO 10326-1 (2016) for translational acceleration or a sit-bar for translational and rotational acceleration, depending on the directions of interest of the specific study. It is, however, important that the transducer used does not alter the dynamic response of the infant car seat or the posture of the infant, as these aspects will influence the vibration transfer path to the infant.

2.3.2 Vibration Quantification

Measurements from vibration transducers are obtained in terms of acceleration-time histories. These acceleration-time histories can be evaluated based upon the peak acceleration or some average representation of the acceleration observed throughout the measurement. The Root Mean Square (RMS) acceleration is widely accepted as a measure to quantify vibrational exposure in the application of human response to vibration. The RMS acceleration measured along a specific direction (k), as defined by Griffin (1990), may be calculated using,

$$A_{RMS,k} = \left[\frac{1}{N}\sum A_k(i)^2\right]^{0.5} \tag{7}$$

where N is the number of sampled acceleration values $A_k(i)$. The RMS acceleration serves as a type of average of the acceleration levels encountered throughout the measurement. This averaging method however does not highlight the effect of peak accelerations, as the effect of these peak values may be masked when the measured signals contain a large number of samples. The Crest Factor (CF) - the ratio of the peak acceleration to the RMS acceleration - is used to quantify the effect of high peak accelerations in the data. It is advised that high CF applications (CF > 6 according to BS 6841 (1987) and CF > 9 according to ISO 2631-1 (1997)) alternative methods to the RMS acceleration be used to evaluate vibration levels. These high CF applications may include transient, shock or non-stationary motions. The Vibration Dose Value (VDV) may serve as an alternative measure of the vibration experienced by a vehicle occupant for high CF applications and may be calculated as,

$$VDV = \left[\frac{T_s}{N}\sum A_k(i)^4\right]^{0.25} \tag{8}$$

where T_s is the vibration duration. The VDV is especially useful in applications where the vibration exposure consists of a combination of high and low vibration levels, for variable durations (BS 6841, 1987).

Standards such as BS 6841 (1987) and ISO 2631-1 (1997) have been developed for the measurement and assessment of human exposure to whole-body vibration. The results from many studies have been used to develop frequency weightings according to the subjective feedback provided by adult test participants on their comfort levels for different vibration frequencies and magnitudes in each of the translational and rotational directions. The remainder of this dissertation will refer to the BS 6841 (1987) standard only. This standard was selected to allow comparison to literature on the difference thresholds of adult humans, or the smallest change in vibration stimulus that can be perceived, for results presented in section 5.2.2 and 5.3.2. The BS 6841 (1987) frequency weightings that are used for the evaluation of discomfort for measurements performed on a vehicle seat are listed in Table 2, while a plot of the frequency weightings may be viewed in BS 6841 (1987). Measured accelerations can be filtered by making use of these frequency weightings to ensure that the effects of the frequencies that have a greater influence on comfort are highlighted. Once the measured accelerations have been filtered with the appropriate frequency weighting curve, typical time-domain parameters such as RMS acceleration and VDV can be calculated and analysed with respect to the appropriate standard. It is, however, unknown whether these frequency weightings will be applicable to infants, as their response to vibration may be different due to differences between the physical and physiological attributes of infants and adults.

Table 2: BS 6841 (1987) frequency weightings applied to accelerations measured at a seat for different translational and rotational directions

Frequency weighting	**Measurement direction**
W_b	z
W_d	x, y
W_e	r_x, r_y, r_z

2.3.3 Infant Car Seat Transmissibility

The manner in which vibration is perceived and the effect of the perceived vibration on health, comfort and activities is highly dependent on the vibration levels to which the occupant is exposed and the manner in which the vibration is distributed throughout the occupant's body. Thus, it is important to determine the transmissibility of infant car seats so that, once the sensitivity of infants to vibration has been established, the vibration levels that are transferred to infants can be assessed and altered if required.

Seat transmissibility is used to relate the vibration transferred to a seated occupant to the vibration input to the seat. This is achieved by comparing the acceleration measured at the occupant-seat interface (output) with the acceleration measured at the base of the seat (input). Thus far, most studies have investigated the vertical transmissibility of vehicle seats and infant car seats, however, transmissibility can be calculated in any direction. Vibration enters an infant car seat from multiple points, and this vibration is again transferred through multiple points to the infant. However, for vertical transmissibility studies it is often assumed that the seat acts as a Single-Input, Single-Output (SI-SO) system (Griffin, 1990). The complex seat transfer function, $H_k(f)$, of the direction of interest (k) can be estimated using the relationship,

$$H_k(f) = \frac{G_{k,io}(f)}{G_{k,ii}(f)} \tag{9}$$

where $G_{k,io}(f)$ is the cross-spectral density between the input and the output measurements, and $G_{k,ii}(f)$ is the Power Spectral Density (PSD) of the input. The modulus, $|H(f)|$, and phase, $\varphi(f)$, may be calculated using the imaginary (Im) and real (Re) parts of the transfer function, as demonstrated in equations (10) and (11).

$$|H(f)| = \sqrt{(Re[H(f)])^2 + (Im[H(f)])^2} \tag{10}$$

$$\varphi(f) = \tan^{-1}\left\{\frac{Im[H(f)]}{Re[H(f)]}\right\} \tag{11}$$

Seat transmissibility can be used to determine the vibration isolating properties of the seat, and the frequencies at which the seat will amplify or attenuate vibration. This is done by plotting the modulus of the transfer function over vibration frequency, and thus identifying the frequencies where the modulus is greater and less than one as the frequencies of amplification and attenuation, respectively. Tests involving adult participants have indicated that the human is more sensitive to lower frequency vibration, typically between 0.25 - 20Hz. This is also reflected by the higher frequency weightings of W_b, W_d and W_e prescribed by BS 6841 (1987) within this frequency range. Vertical transmissibility data have indicated that there are typically low-frequency regions (approximately 4 Hz) where the vibration transferred to the occupant is amplified by the seat, and attenuation at higher frequencies (8 - 12 Hz) (Griffin, 1978). It is desired that the seat attenuate vibration within the frequency range where the occupant is sensitive to vibration. This method of determining vibration transmissibility is also applicable to infant car seats, however, the sensitivity of infants to vibration frequency is still unknown.

In order to capture the dynamic response of a seat, the vibrations levels must be measured with an occupant in the seat. It is not advised to make use of rigid masses or crash tests dummies instead of human participants during biodynamic testing (for example seat vibration transmissibility tests), as the mechanical impedance of these masses are not similar to that of the human body (Smith, 1997). The transmissibility of seats is usually determined from laboratory tests, where the seat can be subjected to various vibration levels and -frequencies that are controlled by the researcher. If the seat materials behave linearly, good transmissibility values will be obtained where the vibration input to the seat and vibration output to the occupant are related well. In the event where transmissibilities are derived from in-vehicle measurements obtained from testing on real road conditions, the reliability of the transfer function needs to be confirmed. This is necessary since the motions associated with real vehicle travel will not have equally distributed energy at all frequencies, as compared to laboratory experiments where the vibration input of interest is selected by the researcher and can be closely controlled throughout the experiment (Griffin, 1990). The ordinary coherence function $\gamma_{k,io}^2(f)$ may be used as a measure of the reliability of the transfer functions, and is calculated using,

$$\gamma_{k,io}^2(f) = \frac{\left|G_{k,io}(f)\right|^2}{G_{k,ii}(f)G_{k,oo}(f)} \tag{12}$$

where $G_{k,oo}(f)$ is the PSD of the output. The values of the coherence function lie within the range [0, 1], where a high coherency value (typically > 0.9) is required to conclude that the acceleration measured at the seat-infant interface is linearly related to the acceleration supplied to the base of the infant car seat. There are many factors that may influence the coherence function, including non-linearities in the transfer of vibration (for example due to non-linear materials used to manufacture infant car seats) as well as noise contained within the acceleration measurements. Another aspect that may influence the coherency observed is the presence of vibration along multiple axes, which may influence the vibration in the axis under question. It was shown by Qiu and Griffin (2004) that, for multiple-axis vibration applications, the coherency may be improved by considering the system of vibration transfer as a Multiple-Input, Single-Output (MI-SO) type system as opposed to the SI-SO approach. Subsequently, multiple coherencies instead of ordinary or partial coherencies, could result in better overall coherency values.

2.4 Characterising Vibrational Response of Infant Car Seats

Infants who are seated in an infant car seat within a vehicle are exposed to vibration during vehicle travel. The vibrations transferred to the infant can be combinations of translational (vertical, longitudinal and lateral) and rotational (roll, pitch and yaw) vibration. Understanding the role of the infant car seat in the transfer of vibration from the vehicle to the infant is important, as the dynamic response of the infant car seat can be altered through design to better isolate the infant from WBV exposure.

Some studies have been performed to characterise the vibration transmitted to infants seated in an infant car seat while driving in a vehicle. A study performed by Giacomin (2000) tested the vibrational response of two seatbelt-fastened infant car seats (one front-facing and one rear-facing), with infants, in a vehicle travelling over two different road surfaces (pave surface and a speed bump). The results from this study showed that, for the vertical direction, the vibration levels measured between an infant car seat and infant are higher than the vibration levels measured between the vehicle seat and driver. This study also indicated that infant car seats amplify vibration at most frequencies within the frequency range 0 - 60Hz when compared to the vibration measured at the vehicle floor. The rear-facing infant car seat that was restrained on the front passenger seat displayed peak acceleration transmissibility factors greater than 400% (Giacomin, 2000). No coherency values were reported for the transmissibilities that were calculated. It must, however, be noted that the vibration levels were measured at different locations in the vehicle (front driver and -passenger seat and rear passenger seat), and that the differences observed in vibration levels and associated transmissibilities may be influenced by these different measurement locations.

The amplification of vibration seen in infant car seats has been linked to the resonance of the materials used to manufacture these seats within lower frequency bands. Another study by Giacomin (1997) showed that the vertical resonance frequency of seatbelt-fastened infant car seat frames can be as low as 15 - 17Hz. It was also observed that at least three modes of vibration were typically encountered in the frequency range up to 40Hz (Giacomin, 1997).

2.5 Conclusions from Available Literature

This literature study has shown that, although there are still many questions in the field of human response to vibration and particularly in a vehicle environment, adult occupants have predominantly been at the centre of these investigations. The responses of infants to WBV cannot be inferred from the results from studies involving adults as participants, as it has been shown that the vibrational response (Giacomin and Gallo, 2003) and the absorbed power (Giacomin, 2005) of small children are different from those of adults. The sensitivity of infants to different vibration frequencies are unknown. This poses a challenge in the evaluation of vibration data for infants, as there are no weighting curves available for infants and the traditional methods, such as paired comparison testing, used to determine the sensitivity of adults to different vibration frequencies will not be applicable. The vibration transferred to an infant seated in a car seat is also different from that which is transferred to the driver of a vehicle (Giacomin, 2000). Although the studies performed by Giacomin (2000) and Giacomin and Gallo (2003) were performed in multi-axis vibration environments, only the vertical transmissibility of the infant car seats were considered. To date, no studies have considered multi-axial vibration transmissibility of infant car seats. Including the vibration transferred in directions other than the vertical may assist in explaining the changes in posture that infants typically display while travelling in infant car seats. Some studies have shown that an infant's cardiorespiratory response is dependent on his or her posture while being seated in a stationary infant car seat, and it is possible that the effect of infant car seat inclination angle observed by Arya et al. (2017) is related to the posture of the infant. The study by Arya et al. (2017) has also indicated that the presence of vertical vibration has a negative influence on the cardiorespiratory response of infants. No relationships have, however, been established between multi-axis infant car seat vibration, infant posture and cardiorespiratory response.

Chapter 3: Problem Statement and Study Overview

The voids identified from the literature presented in Chapter 2 are used to formulate a problem statement. This problem statement is broken down into different aspects, that are each associated with different objectives that will need to be achieved when investigating the response of infants to vehicle vibration. The remainder of this study addresses specifically selected objectives identified from this section.

3.1 Problem Statement

A void in current literature has been identified - the complex relationship between multi-axis vibration input to a new-born infant seated in an infant car seat, and the resultant changes in posture and cardiorespiratory response of the infant. The multi-axis vibration input in question is the vibration transferred to the infant while he or she is seated in a vehicle travelling along a typical suburban road. A second void has therefore been identified - the multi-axis transmissibility of an infant car seat.

3.2 Study Overview

In order to understand the context of the work presented in this dissertation, the problem needs to be addressed holistically. In doing so, the problem statement can be broken down into four main aspects, which are depicted in Figure 3. Figure 3 also describes the link between different aspects (the Why), different parameters that would need to be addressed to describe the aspects (the What) as well as the means with which these parameters can be addressed (the How).

As can be seen in Figure 3, the first aspect, or foundation, of a study investigating the response of infants to vehicle vibration is based upon the field of human response to vibration within a vehicle environment. Literature has shown that, if one aims to investigate the response of humans to WBV associated with vehicle travel, one must first characterise the environment in which the occupant is situated (Griffin, 1990). Certain events that are associated with vehicle travel that may lead to a change in posture and/or the cardiorespiratory response of an infant need to be identified. These events are included as inputs to the vehicle by means of the mission profile selected for the study. It is thus important that the selected mission profile is characterised to understand its vibration content. The resultant vibrational response of the vehicle sprung mass, as well as possible confounding factors such as the noise levels and temperature within the vehicle, need to be measured. The measured vibrational response of the vehicle can also be related to the events encountered along the mission profile, while these events may, in turn, be related to the response of infants. Although the possible confounding factors only need to be evaluated when infants are participating in tests, the vibrational response of the vehicle sprung mass can be characterised without including infants as participants.

The response of the vehicle sprung mass will provide vibration input to the infant car seat, which would in turn transfer the vibration to the infant based upon the properties of the seat as well as the properties of the vibration exposure. In order to understand the postural- and cardiorespiratory responses of infants subjected to vehicle vibration, the vibration input to the infant needs to be fully understood. Multi-axis vibration is encountered during vehicle travel under typical driving conditions. Although the vertical transmissibility of infant car seats has been evaluated (Giacomin, 2000, Giacomin and Gallo, 2003), the multi-axis transmissibility has not been established yet. The vibrational response of the vehicle body is transferred to the infant car seat through the vehicle seat. The translational vibration at the vehicle seat-infant car seat interface and the infant-seat interface can be measured using a seat pad accelerometer. The rotational acceleration of the interfaces can be estimated from the accelerometers used to instrument the vehicle and the base of the infant car seat, respectively. The multi-axis transmissibility of the vehicle seat-infant car seat system can be determined by relating the vibration at the vehicle seat-infant car seat interface (input) to that at the infant-seat interface (output). The resultant transfer functions will then indicate the frequencies at which the vehicle seat-infant car seat system amplifies or attenuates the vibration transferred to infants. If the response of infants can be linked to specific events encountered along roads, specific vibration directions or ultimately, the vibration frequency associated with the response, this knowledge can be used to improve the design of infant car seats. Although it is preferable that infants are included in these tests, valuable results can still be obtained for tests that do not include infants as participants.

Once the input to the infant is well understood, the subsequent responses need to be investigated. Literature has shown that the posture of an infant affects their cardiorespiratory response in a stationary infant car seat (Tonkin et al., 2003), while being exposed to vertical vibration has a negative influence on their cardiorespiratory response (Arya et al., 2017). The posture and cardiorespiratory response of infants have, however, not been investigated under real driving conditions, where the infants are subjected to multi-axis vibration. It is postulated that the direct response of the infant to the motion input would be manifested as a change in posture. This change in posture can be measured during testing by making use of cameras. Although this posture-tracking analysis would include infants as participants, a preliminary analysis of the effect of multi-axis vibration on the posture of an infant can also be performed by making use of a biodynamic model. The cardiorespiratory response of an infant, as a result of the multi-axis vibration input, the change of posture of the infant or a combination of these two effects, can be monitored during testing.

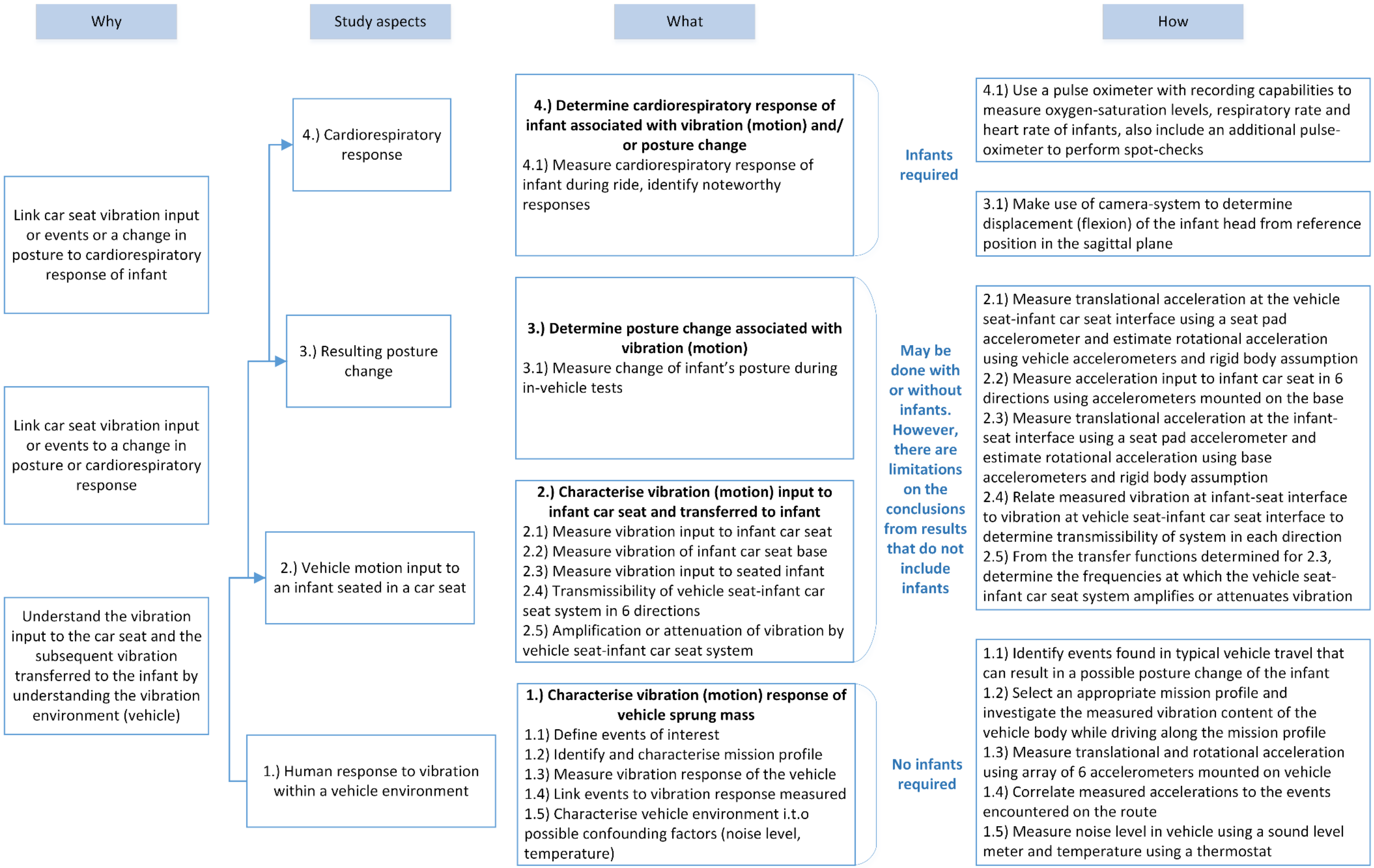

Figure 3: Overarching study overview

3.3 Aim of Study

The primary aim of the study is to propose a thorough method for an investigation into the effect of vehicle vibration on the posture and cardiorespiratory response of infants.

The secondary aim of the study is to quantify the multi-axis vibration input to infants encountered under real driving conditions (Study aspect 2 in Figure 3).

The tertiary aim of the study is to add to the limited body of knowledge of the multi-axis transmissibility of infant car seats to in-vehicle multi-axis vibration exposure (Study aspect 2 in Figure 3).

The quaternary aim of the study is to establish the effect of multi-axis vehicle vibration on the posture and cardiorespiratory response of a healthy, term infant who is seated in an infant car seat during vehicle travel (Study aspects 3 and 4 of Figure 3).

3.4 Study Objectives

3.4.1 Method for Investigating the Response of Infants to Vehicle Vibration

1. Develop a detailed method that can be implemented in a study investigating the effect of vehicle vibration on the posture and cardiorespiratory response of infants

The following objectives have been identified from the "What" section of Figure 3. These objectives are necessary to address each of the aspects identified for the study.

3.4.2 Human Response to Vibration within a Vehicle Environment

2. Quantify the characteristics of the vehicle environment in terms of vibration while driving along a road with specific inputs
3. Quantify sound and temperature as possible confounding factors while driving along a road with specific inputs

3.4.3 Vehicle Motion Input to an Infant Seated in an Infant Car Seat

4. Quantify the multi-axis vibration input to the infant car seat during vehicle travel (at vehicle seat-infant car seat interface) in terms of the vibration magnitude and frequency

5. Quantify the multi-axis vibration transferred to an infant seated in an infant car seat during vehicle travel (at the infant-seat interface) in terms of the vibration magnitude and frequency
6. Quantify the multi-axis transmissibility of the vehicle seat-infant car seat system during vehicle travel in terms of modulus, phase and coherency
7. Identify the frequencies at which the vehicle seat-infant car seat system amplifies or attenuates vibration to the infant

3.4.4 Resulting Posture Change

8. Quantify the change in posture of an infant while being seated in an infant car seat responding to multi-axis vibration
9. Determine if this change in posture can be associated with specific vibration inputs

3.4.5 Cardiorespiratory Response

10. Quantify the continuous cardiorespiratory response of an infant while engaged in different activities
11. Determine if a change in the cardiorespiratory response can be associated with different activities of the infant
12. Determine if there is a correlation between the frequency of noteworthy response events (defined in section 0) and the activity of the infant
13. Determine if a change in the cardiorespiratory response can be associated with a change in posture
14. Determine if a change in the cardiorespiratory response can be associated with the different components of vibration input to the infant

3.5 Study's Hypotheses

When an infant is seated in an infant car seat travelling in a vehicle, the infant will experience a certain level of vibration inputs as a result of the road inputs to the vehicle and the subsequent transfer of vibration from the vehicle body to the infant. Three hypotheses have been formulated regarding the possible responses of the infants to the vibration exposure. These hypotheses are listed below and are also depicted in Figure 4.

1. The combination of the multiple-axis vibration inputs to the infant will result in a change in posture of the infant.
2. This change in posture will then result in a reduction of the size of the airway of the infant, resulting in a change in the cardiorespiratory response of the infant.
3. Multi-axis vibration exposure directly influences the cardiorespiratory response of the infant.

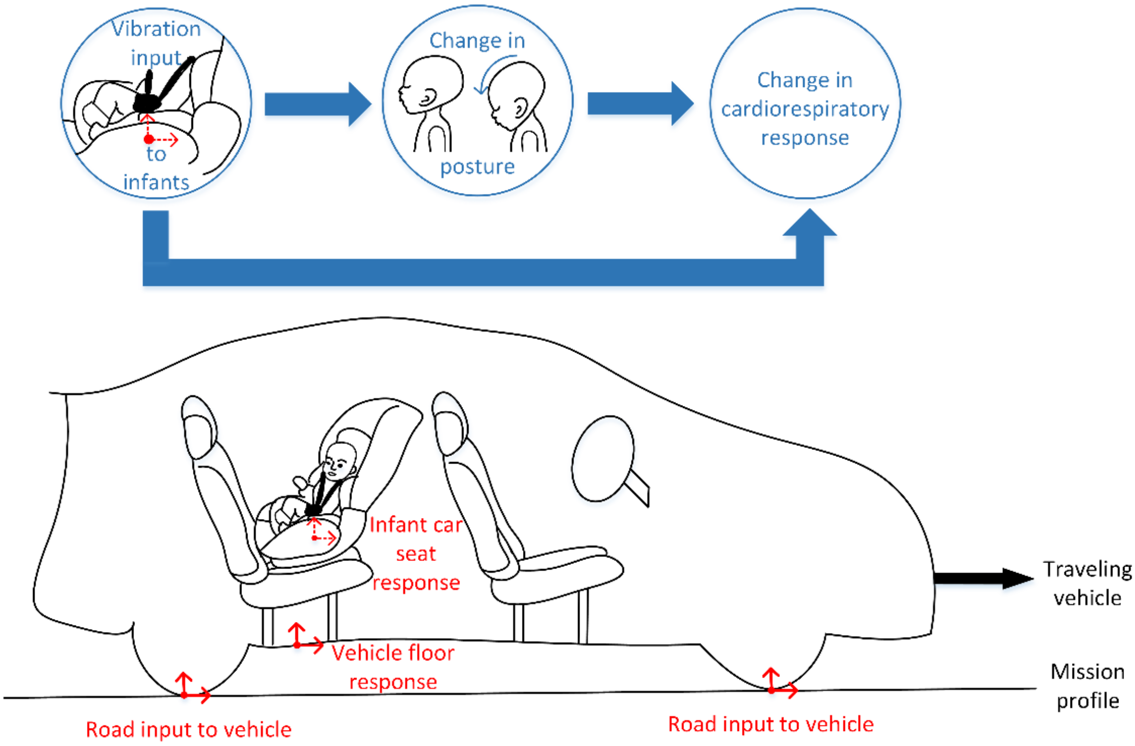

Figure 4: Depiction of the hypothesised chain of events resulting in a change in cardiorespiratory response of infants travelling in a vehicle

3.6 Conclusion

The following problem statement has been identified for this study: "*Determining the complex relationship between multi-axis vibration input to a new-born infant seated in an infant car seat, and the resultant changes in posture and cardiorespiratory response of the infant*." An overview was presented for a study investigating the effect of vehicle vibration on the response of infants. The main aspects that would need to be addressed in such a study include characterising the vibration environment (vehicle), characterising the transfer of vibration by the infant car seat, determining the posture change of the infant and measuring the cardiorespiratory response as a result of posture change and/or the vibration inputs. It is the hypothesis of the researchers that the multi-axis vibration encountered during driving will result in a change in posture of an infant, and that this change in posture and/ or multi-axis vibration exposure will result in a change in the cardiorespiratory response of the infant. The aims addressed by this study include proposing a method to investigate the effect of vehicle vibration on the posture and cardiorespiratory response of infants, quantifying the multi-axis vibration input to infants under real driving conditions and subsequently determining the multi-axis transmissibility of an infant car seat under real driving conditions. These aims can be reached by addressing Objective 1, 2, 4, 5, 6 and 7. The proposed methodology will be detailed in Chapter 4, with the in-vehicle vibration input to an infant documented in Chapter 5 and infant car seat transmissibility presented in Chapter 6.

Chapter 4: Proposed Method for Investigating the Response of Infants to Vehicle Vibration

A study that investigates the response of infants to vehicle vibration is a complex research problem as there are multiple factors that may influence this response. A comprehensive, well-thought-out method is therefore needed to ensure that meaningful results can be acquired from such a study. This section will present the proposed experimental design, setup and procedures for such a method.

4.1 Experimental Design

The following section will document important considerations of the experimental design of a study investigating the response of infants to vehicle vibration.

4.1.1 Study Design

A study investigating the response of infants to vehicle vibrations will be an analytic observational study, specifically a cross-sectional type. During this study, cardiorespiratory responses and posture will be observed for infants who are seated in a car seat in a vehicle travelling along a typical suburban road. The vibration levels to which the infants will be exposed during the trip will also be measured.

4.1.2 Study Population

The study will be comprised of healthy, term infants. The infants would typically be a few hours to a few days of age upon testing. Both male as well as female participants will be included in the study. Participants from all ethnic groups that can be recruited from the participating hospital will be included in the study. Each infant will act as his/her own control, as the cardiorespiratory measurements taken during the tests of interest will be adjusted for the baseline measurements of the infant in a cot in the supine position.

4.1.3 Required Sample Size

A study performed by Arya et al. (2017) indicated that a medium effect size of 0.55 can be expected. Using G*Power (version 3.1.9.2), with an effect size 0.55, at an alpha level of 5% and a power of 80% indicated that a total sample size of 27 should be sufficient to ensure strong statistical tests. It was therefore recommended by a consulting statistician to use a minimum sample size of 30 participants.

4.1.4 Inclusion and Exclusion criteria

The following section describes the inclusion and exclusion criteria that should be applied during prenatal- and postnatal recruitment of participants. The criteria used to terminate testing in the event of a potentially harmful cardiorespiratory response being observed is also presented.

Prenatal Recruitment

The following exclusion criteria should be used during the recruitment of possible participants:

Table 3: Prenatal screening exclusion criteria

Exclusion criterion	**Reason for exclusion**
High-risk pregnancies, where a significant risk exists that the infant will be born before 37 weeks gestational age	To ensure minimal risk of loss of recruited participants due to complications during birth
	To ensure the infant is healthy and does not have an increased risk of displaying a negative cardiorespiratory response
Parents who have previously lost a child to Sudden infant death syndrome (SIDS)	To ensure the infant is healthy and does not have an increased risk of displaying a negative cardiorespiratory response
Parents who have a combined income < R3500	To prevent the transportation home becoming an undue incentive to get parents to partake in the study against their better judgement
Parents who live outside a 30km radius from the participating hospital	To limit the time required to perform each test

Postnatal Recruitment

Once the infants who have been recruited during the prenatal recruitment phase are born, additional inclusion criteria may be used to identify the infants who can take part in the study.

The infants included in the study will need to be new-born, full-term and healthy infants who are ready for hospital discharge. A healthy infant is defined as having not been admitted to the neonatal ward of the hospital, displaying normal oxygen saturation levels while in hospital, having a 5-minute Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score ranging from 8 to 10 and weighing within the weight range corresponding to the relevant gestational age as displayed in Table 4. The minimum and maximum values were calculated as:

$$[Min, Max] = \mu \pm 2\sigma \tag{13}$$

The exclusion criteria listed in Table 5 may also be applied for the selection of healthy, viable test participants.

Table 4: Minimum and maximum allowable weight for inclusion to the study per gestational age and sex (adapted from Janssen et al. (2007))

Sex	Gestational age at birth [weeks]	Minimum weight [g]	Maximum weight [g]
Male	37	2467.8	4205.0
	38	2526.8	4192.0
	39	2665.4	4506.6
	40	2866.6	4508.6
	41	3108.3	4645.9
Female	37	2222.5	3878.9
	38	2446.9	4140.1
	39	2587.8	4323.8
	40	2723.1	4555.9
	41	2800.8	4592.8

Table 5: Postnatal screening exclusion criteria

Exclusion criterion	Reason for exclusion
Pre-term infants	To eliminate the variability associated with the pathological reasons responsible for the early birth
	To ensure the infant is healthy and does not have an increased risk of displaying a negative cardiorespiratory response
Infants displaying any signs of cardiorespiratory disease	To ensure the infant is healthy and does not have an increased risk of displaying a negative cardiorespiratory response
Infants displaying Hypotonia	To ensure that the infant is not more prone to developing bad posture during the study period and thus put the infant at increased risk of developing negative cardiorespiratory responses
Infants with known congenital anomalies	To ensure the infant is healthy and does not have an increased risk of displaying a negative cardiorespiratory response
Infants who have displayed significant events of apnoea prior to testing (see definition of these events in Table 7)	To ensure the infant is healthy and does not have an increased risk of displaying a negative cardiorespiratory response
Infants admitted to the Neonatal Intensive Care Unit (NICU) of the hospital	To ensure the infant is healthy and does not have an increased risk of displaying a negative cardiorespiratory response

During Testing

Any infants who display an apnoea (see Table 7) during any phase of testing will not be allowed to proceed to the next phase of testing.

4.1.5 Variables of Interest

Vibration Measurements

When evaluating the vibration input to an infant during vehicle motion, the vibrational response of the vehicle body as well as that of the infant car seat need to be quantified. As the infant may be subjected to multiple axis vibration, the response of the vehicle body and infant car seat may be quantified for each of the translational and rotational directions of interest. A total of 6 acceleration measurements consisting of 3 translational (A_x, A_y, A_z) and 3 rotational (r_x, r_y, r_z), will be gathered for the vehicle body as well as the infant car seat.

Posture Measurements

The posture measurements may include angular displacement of the head of the infant in the sagittal plane from the reference position (φ_s), as is described in Figure 5. Due to the support of the infant car seat at the back of the infant's head, the infant's neck will only be able to perform flexion, not extension, as shown in Figure 5.

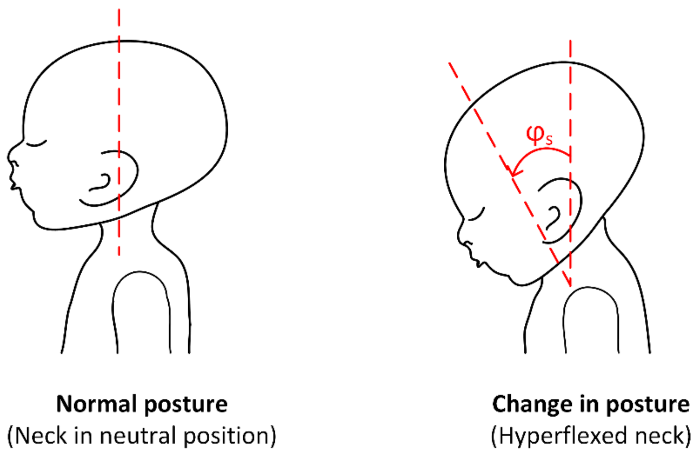

Figure 5: Definition of change in posture in the sagittal plane

Cardiorespiratory Measurements

The cardiorespiratory measurements of interest have been identified from past studies, as summarised in section 2.2.4. These measurements include the heart rate (HR), respiratory rate (RR) and blood oxygen saturation levels (SpO_2) of the infant. These measurements have been selected in accordance with the recommendations by the AAP (1999) for the observation of possible bradycardia, oxygen desaturation or apnoea during the ICSC. Although apnoeas are common under preterm infants as a result of underdeveloped respiratory systems, it may also serve as an indication of the presence of disease or cardiorespiratory compromise and must therefore be monitored (Matiz and Roman, 2003). HR, RR and SpO_2 should therefore be monitored continuously throughout testing. Noteworthy events, which may serve as indicators of the decline in the cardiorespiratory response of the infants, are defined based upon the definitions used by Arya et al. (2017), to allow for the comparison of results.

Table 6: Definition of noteworthy events that may be observed (based upon definitions used in Arya et al. (2017))

Noteworthy event	**Definition**
Periodical breathing	Pause in breathing > 10s
or	
Bradycardia	Heart rate < 100 bpm
	Fall in Heart rate > 30 bpm from baseline measurement
or	
Oxygen desaturation	Fall in SpO_2 ≥4% from baseline measurement for ≥ 10s
	SpO_2 < 85% for ≥4s

For a study including infants as participants, defining a threshold of cardiorespiratory response where testing will be terminated to prevent the infant from harm, is a crucial consideration. The definition of these thresholds is typically conservative, especially due to the highly vulnerable nature of infants. The observation of an apnoea may be used as termination criteria for tests, as an apnoea is an indication of the infant's health being compromised. The definitions of an apnoea are based upon the definitions used by Arya et al. (2017) and Eichenwald (2016), as these definitions are conservative and would pose the lowest risk for the infants involved in the study. These definitions can be seen in Table 7.

Table 7: Definition of apnoea governing the termination of tests (based upon definitions used in Arya et al. (2017) and Eichenwald (2016))

Parameter associated with the definition of an apnoea	**Definition**
Periodical breathing	Pause of breathing > 15s
and	
Bradycardia	Heart rate < 100 bpm
	Fall in heart rate > 30 bpm from baseline measurement
and	
Oxygen desaturation	Oxygen saturation < 85%

If all three of these parameters are noted during testing, i.e. a periodical breathing, followed by a decrease in heart rate and a decrease in oxygen saturation levels, a procedure will need to be initiated to protect the participants from any adverse risks due to their cardiorespiratory response.

Statistical Formulation of Variables

A study investigating the response of infants to vehicle vibration will consist of response (dependent) and predictor (independent) variables. The response variables can either be categorised as continuous (HR, RR and SpO_2) or categorical (frequency of noteworthy response events). The predictor variables may either be categorised as being continuous (change in posture and different components of acceleration measured as input to the infant) or categorical (the three different tests that are performed). A summary of the variables can be seen in Table 8.

Table 8: Statistical variables of study

	Variable	Variable type	Description of variable
Response	HR	Continuous	Continuous measurement of parameter in response to test
	RR		
	SpO_2		
	Apnoea	Categorical	Frequency of noteworthy event encountered throughout testing
	Bradycardia		
	Fall in SpO_2 > 4%		
Predictor	Posture: Head angular displacement in sagittal plane	Continuous	Continuous measurement used to predict response
	Posture: Head angular displacement in frontal plane		
	A_x		
	A_y		
	A_z		
	r_x		
	r_y		
	r_z		
	Baseline test	Categorical	Response predicted based upon different categories
	Static car seat		
	In-vehicle tests		

4.2 Experimental Setup

4.2.1 Vehicle

A vehicle with at least a 3-star new car assessment program (NCAP) rating should be used for the tests, meaning that the vehicle will have average to good occupant protection. The selected vehicle should be able to seat at least 5 occupants, including two researchers, the two parents of the infant and the infant in his/her car seat. A vehicle that meets the criteria set above and to which the researchers have access is a 2007 Toyota Quantum d4d and was used in the current study. Some of the properties of this vehicle are provided in Table 9.

Table 9: Test vehicle properties

Parameter	**Description**
Vehicle mass (unladen)	2060kg
Suspension	Original
Tyre pressure	2.7 bar
Vehicle Dimensions	
Height	2.105m
Length	4.840m
Width	1.880m
Odometer reading	87800km

The vibrational response of the vehicle sprung mass was measured by making use of three linear triaxial accelerometers, namely the CXL04GP3 4g accelerometer range manufactured by MEMSIC. These are DC-type accelerometers with a frequency bandwidth of 0 - 100Hz. The accelerometers were arranged such that translational and rotational acceleration of the vehicle sprung mass can be measured (see section 2.3.1 for details). The placement of the three accelerometers ($A_{v,0}$ to $A_{v,3}$) can be viewed in Figure 6. These accelerometers were rigidly mounted to the vehicle seat frame, which in turn was rigidly mounted to the vehicle floor. This provides a good representation of the response of the vehicle sprung mass. For tests involving infants as participants, the vehicle environment may also be measured in terms of sound levels (using a sound level meter) and temperature (using a thermostat) to detect if the response of the infant may be a result of startling due to loud noises or a large change in the ambient temperature.

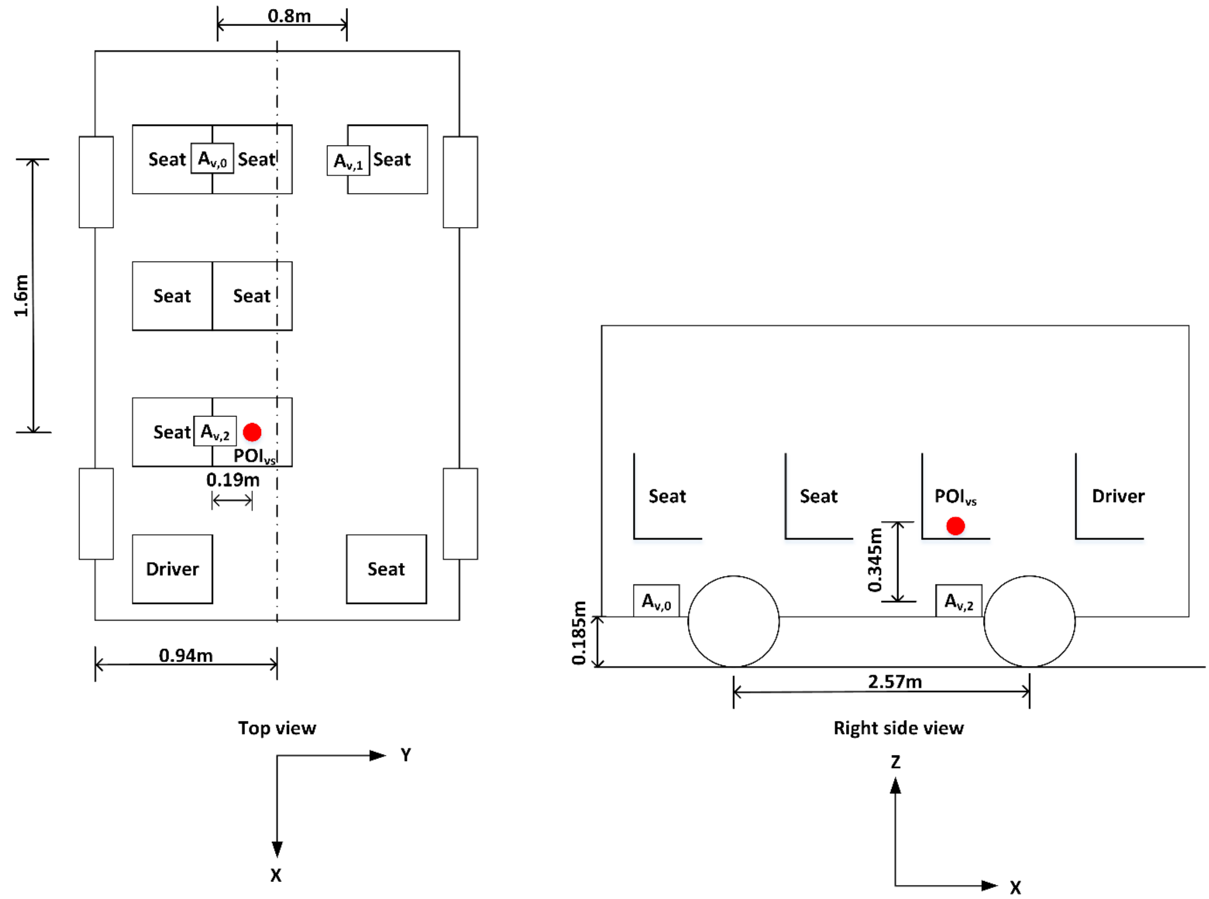

Figure 6: Accelerometer configuration in test vehicle to obtain sprung mass response

4.2.2 Infant Car Seat

The infant car seat that has been identified for use in the current study is the Chelino Spin 360, which is a rear-facing ISOFIX infant car seat. The infant car seat is compliant with ECE R44/04, which regulates the approval of restraining devices for child occupants of power-driven vehicles and bears a certification mark (European Union, 2005). The vehicle selected for the study does not have ISOFIX anchor points for an ISOFIX car seat. The researchers have therefore acquired a retrofit ISOFIX bracket from the ISOFIX Bracket Company that has been tested according to ISO 13216-1 (1999).

The infant car seat was also instrumented with accelerometers which could be used to characterize the vibration input to the infant. A set of three accelerometers was rigidly connected to the steel frame of the base of the infant car seat to measure translational vibration entering the base and to estimate the rotational acceleration of the infant car seat, as can be seen in Figure 7. Care was taken to ensure that the addition of these accelerometers do not compromise the functioning of the infant car seat and would not pose any threat to an infant. An additional set of accelerometers may be placed closer to the infant (either under the infant in the form of a seat pad accelerometer or sit-bar, or wrapped in the infant's blanket or on a clothing piece of the infant) to measure the vibration input to the infant.

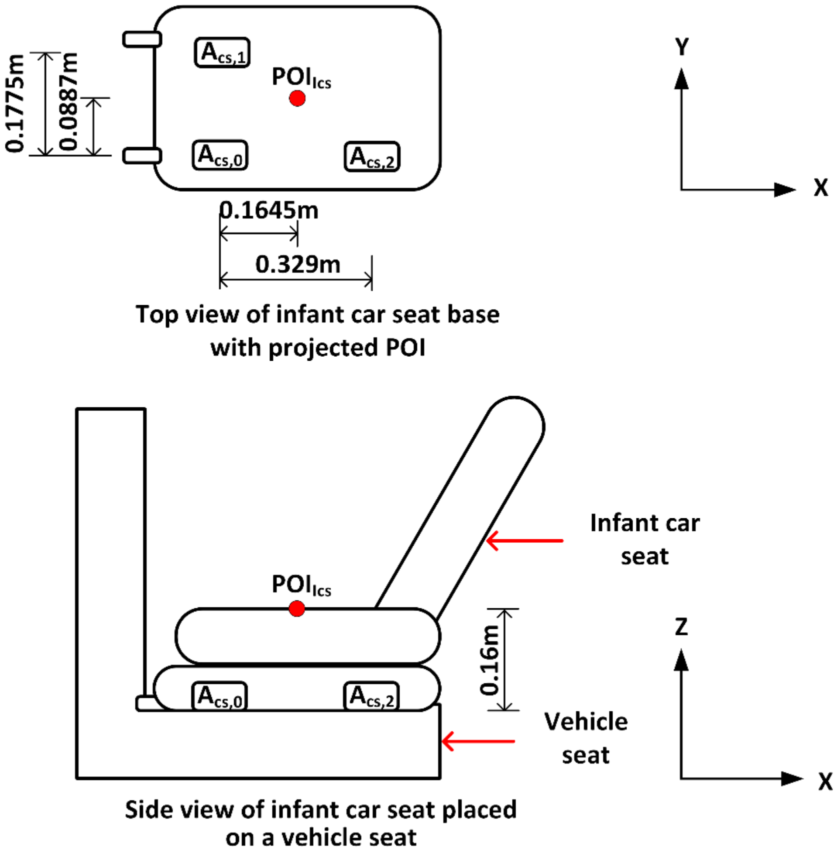

Figure 7: Accelerometer instrumentation of car seat base

All sensors that are used within the vicinity of the infant will need to be hermitic or bear an ingress protection (IP) rating, as defined by SANS 60529 (2013), such that the sensors are protected from liquid ingress. This will require an IP rating > X4, where the second digit is indicative of the protection of a sensor from liquid ingress and an IP rating of X4 will ensure that water splashing around the enclosure of the accelerometer will not have a harmful effect (Bisenius, 2012) . This safety measure will ensure that the infant is protected from any possible electric shock in the event of nappy failures.

4.2.3 Posture Measurements

The posture of the infant will be tracked with a stereo-vision camera system. The camera will be set up at an angle such that motion in the sagittal (fore-and-aft) plane can be tracked (see Figure 5). A beanie with distinct markers will be placed on the head of the infant, with the position of these markers tracked using a point tracking algorithm. A change in the posture (φs) of the infant can then be defined based upon the angular displacement of the infant's head (in the sagittal plane) from the reference position (infant's head resting against the car seat pillow with the head and body parallel to the sagittal plane as can be seen in Figure 8).

Figure 8: Reference position for infant posture measurement (image adapted from Amazon (n.d.))

4.2.4 Cardiorespiratory Measurements

A pulse oximeter that can record the cardiorespiratory responses of interest (HR, RR and SpO_2) will need to be used for studies involving infants as participants. An additional pulse oximeter may be needed to perform spot checks of the measurements obtained from the primary pulse oximeter recording system. All pulse oximeters used will need to be compliant with SANS 80601-2-61 (2014), which states the requirements for basic safety and essential performance of pulse oximeter equipment (South African National Standard, 2014). The noteworthy response events, as defined from the continuous cardiorespiratory measurements (see section 0), and the frequency at which these events occur will either need to be captured by the measurement equipment or by performing post-processing of the measured responses. All sensors used to measure the cardiorespiratory responses must be non-invasive, which implies the use of contact-type sensors.

4.2.5 Data Acquisitioning

A VBOX (VBOX 3i Dual Antenna RTK, RACELOGIC) system was used to record the vehicle speed, GPS coordinates and angular velocity during testing in the current study. The angular rates of the vehicle were obtained by making use of an inertial measurement unit (IMU), while the vehicle position was measured using two antennas. Both the IMU as well as the antennas form part of the VBOX system. The VBOX made use of a sampling frequency of 100Hz. A MicroAutoBox (MicroAutoBox II 1401, dSPACE) making use of dSPACE software was used for the data acquisitioning. Accelerometers located within the vehicle and the base of the infant car seat were sampled at a sampling frequency of 1 kHz. The measurement systems did not make use of anti-aliasing filters, however a sampling frequency much higher than the frequency of interest was selected to limit the effect of aliasing.

4.3 Study Procedures

4.3.1 Ethical Clearance

Before any study involving humans as participants or informants can commence, it is first required that ethical approval be granted from all the required governing bodies of interest. As a study investigating the response of infants to vehicle vibration would be multi-disciplinary in nature, it would entail that ethical approval be obtained from various Research Ethics Committees (RECs) within the institution where the research would be performed, as well as the participating hospital. The process followed is depicted in Figure 9.

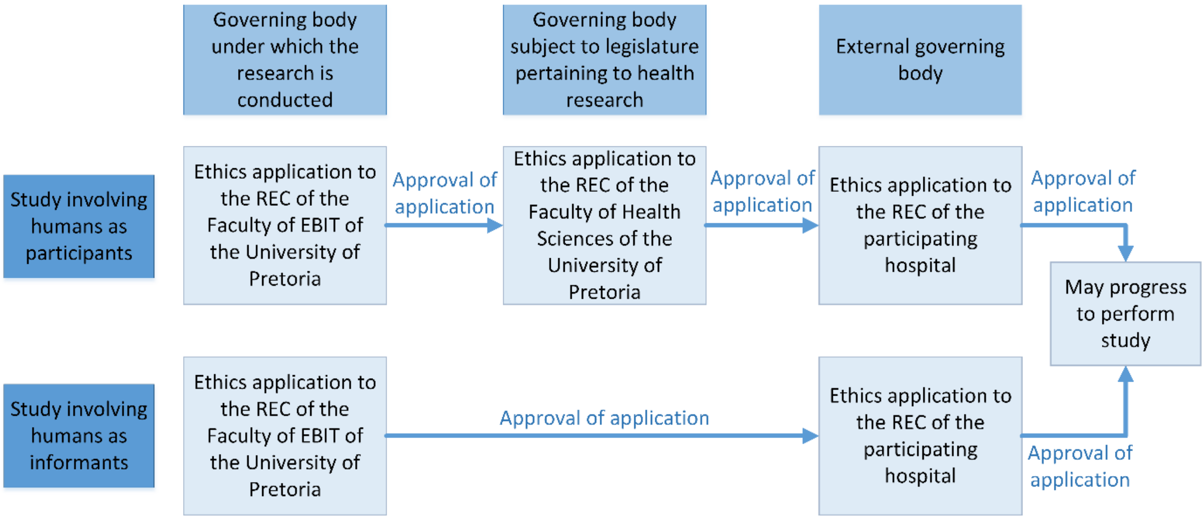

Figure 9: Process for ethics applications

Ethical clearance was obtained from all the institutional governing bodies for a study including infants as participants. Ethical clearance was also obtained to perform an opinion poll that includes prospective parents as informants. The ethical approvals may be viewed in Appendix A. The dates until which the ethical clearances are valid are listed in Table 10.

Table 10: Dates until which the obtained ethical clearance is valid

	Faculty of EBIT REC	**Faculty of Health Sciences REC**	**Participating hospital REC**
Opinion poll	04/03/ 2020	N.A.	20/04/2022
Study involving infants as participants	25/01/ 2020	07/04/2020	29/10/2022

4.3.2 Recruitment Procedure

The participants will be identified and recruited through a trained gynaecologist or midwife in association with the participating hospital or midwifery practice during the antenatal visits of expecting parents. Based on the study risk assessment which can be viewed in Appendix B, it is anticipated that at least 60 participants would need to be recruited to ensure that approximately 30 participants will take part, as required for the statistical analyses. The gynaecologist or midwife will recruit possible participants by identifying low-risk pregnancies as well as applying the exclusion criteria described in Table 3, after which the parents will be informed about the study. A video will be provided to parents that will supply them with information regarding the study and the procedures that will be followed. A recruitment video that was created by the researchers can be viewed using the following YouTube link: https://www.youtube.com/watch?v=LbKzqHYTV-Q. The video was also created with the necessary consent from all parties involved in the production of the video (see Appendix C). An informed consent document will then be presented, which will contain additional information for interested parents. Informed consent documents for the opinion poll as well as a study involving infants as participants can be viewed in Appendix D. If the parents are willing to partake, their contact details will be provided to the researchers.

4.3.3 Opinion poll

A consulting statistician advised the use of an opinion poll to gauge the interest of prospective parents to participate in the study. The feedback from this poll would then be used to update the informed consent and/or experimental protocol to ensure that parents are comfortable with the study. This poll would also serve as an indication of the feasibility of the study in terms of the recruitment of participants.

The online-based opinion poll was distributed at the participating hospital and midwifery practice during the antenatal and postnatal visits of parents. Although the opinion poll has been distributed since May 2019 at the midwifery practice, participation in the opinion poll has been poor, with only one person completing the poll by November 2019. Investigation into the reasons for this is in process.

4.3.4 Pre-test Procedure

The flow diagram depicted in Figure 10 serves to describe the basic layout of the testing procedure that may be followed in a study involving infants as participants. This procedure follows the infant through the entire study, from recruitment, baseline tests, measurements in a static infant car seat, in-vehicle measurements, to the infant possibly being taken home. If an apnoea is noted during any of these phases (orange arrow), which is not the result of the pulse oximeter sensor losing contact, the infant will need to be excluded from all further tests and a procedure must be followed to normalise the infant's response (see section 4.3.5 on p. 45 for procedure).

All the procedures associated with different phases of testing are discussed in the section to follow. These phases include the preparation for tests, baseline tests, static infant car seat tests, in-vehicle tests as well as the procedures that may be followed in the event of an apnoea observed.

Vehicle Preparation

The calibration and functioning of the sensors within the vehicle, the accelerometers fitted to the car seat as well as the data acquisitioning systems will need to be confirmed with independent tests prior to the commencement of testing. This will be done by driving along a standardised piece of road and comparing the measurements to baseline measurements, as well as performing spot checks that all the measurement channels are providing readings. The condition of the vehicle must be inspected prior to testing to ensure the vehicle is safe to drive. The inspections must include checking tyre pressure, tyre wear, the functioning of the head lights, indicators, brake lights and windshield wipers.

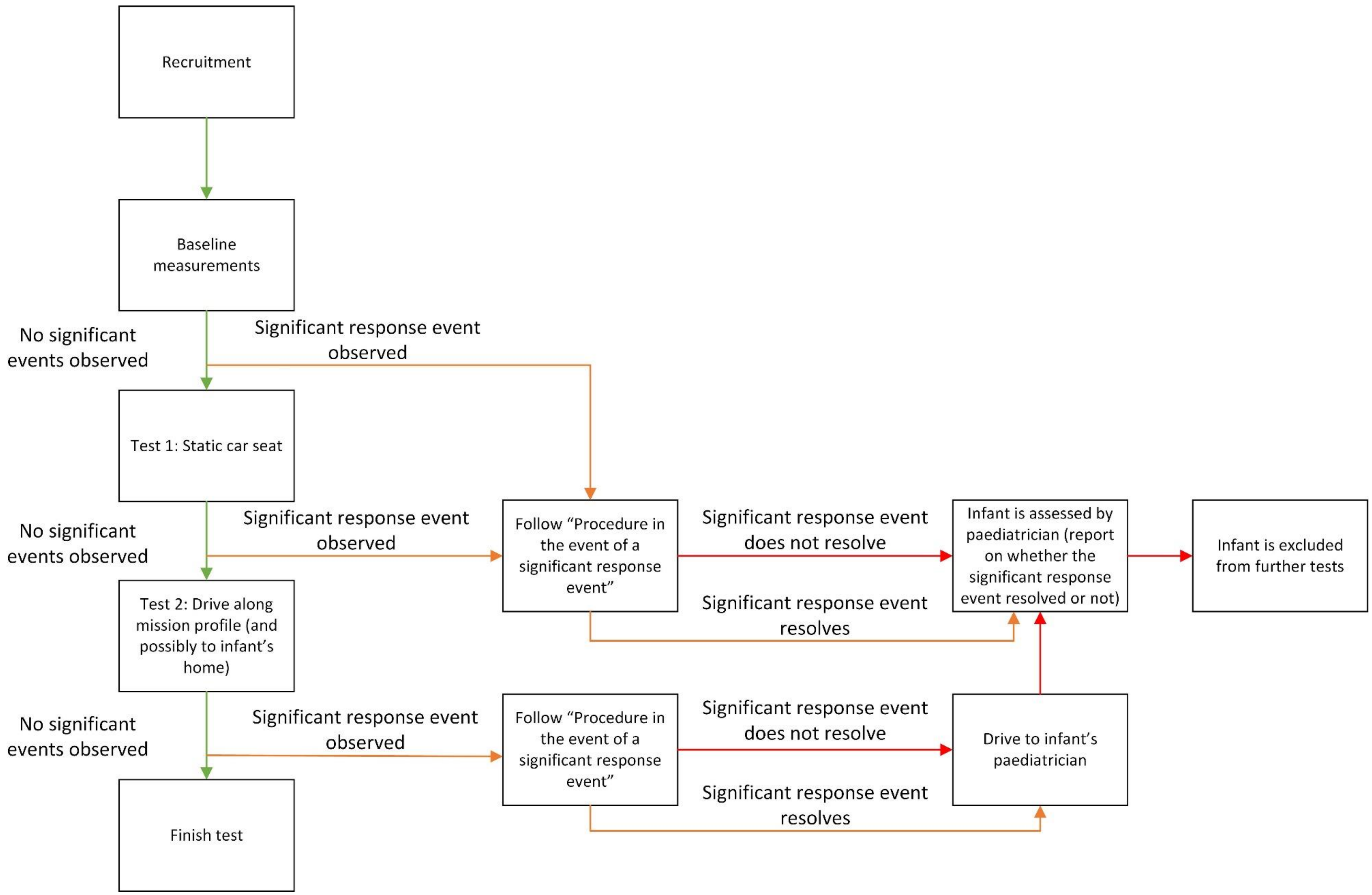

Figure 10: Basic layout of proposed testing procedure

Infant Preparation

The infants participating in the study will need to be fed at least 30 minutes prior to testing. This will ensure that the infant is less likely to be restless during testing. The beanie used to track the posture of the infant will then be secured on his/her head. The state of consciousness of the infant (as defined in Table 11) will need to be noted at the start of the test, with any change in this state and the time at which the state changed noted throughout testing. The nasal cavities of the infants must be checked to ensure that they are clear from any obstructions.

Table 11: Definition of infant state of consciousness (adapted from Brazelton and Cramer (1991))

	State	**Description of state**
1	Deep sleep	Infant's eyes are firmly closed, deep and regular breathing in the absence of motor activity. Infant may give brief startles but will not wake up.
2	Active sleep (Rapid eye movement or REM sleep)	Eyes closed with slow, rotating movements that can be observed. Body can display a range of activities, from minor twitches to short periods of stretching. Irregular, shallow and fast breathing can be observed. Some facial movements (frowns, smiles, mouth movements and sucking) can be observed.
3	Drowsy	Eyes may open or close (partially or fully open) but will appear dazed. Smooth motion of arms and legs can be observed. Regular breathing that is shallower and faster when compared to sleep. When stimulated, they can be brought to a more alert, responsive state.
4	Awake, alert	Infant's face and body are quiet and inactive with bright and shining eyes. Visual and auditory stimuli will result in predictable responses
5	Alert but fussy	Transitional state to crying. Infants are available to external stimuli and may be soothed or brought to the awake, alert state by attractive stimuli. May resort back to fussing if stimuli are

		excessive. Movements are disorganised and jerky and may startle themselves.
6	Crying	At least four types of cries (pain, hunger, boredom, discomfort) which attracts a caregiver.

The pulse oximeter sensor must then be connected to the foot of the infant while in his/her cot. Cardiorespiratory measurements will then be taken to ensure the equipment is functioning correctly. Special attention must be paid to the connection of the sensors to the infants. An additional pulse oximeter will also need to be used to perform a spot check of the measurements obtained from the primary recording system.

4.3.5 Test Procedure

The following section documents the proposed procedures for each of the different phases of testing. The procedures to be followed in the event of an apnoea being observed during any of the testing phases are also described. All safety considerations that should be taken into account for tests involving infants can be viewed in Appendix E. A breakdown of the expected time required for each test can be viewed in Table 19 in Appendix F. A typical schedule for a day of testing 3 infants can also be viewed in Table 20 of Appendix F.

Baseline Measurements

The HR, RR and SpO_2 of the infant in the supine position in his/her cot will be measured for 30 minutes using the primary pulse oximeter.

Test 1: Static Infant Car Seat Measurements

As can be seen in Figure 10, the infant may only advance to Test 1 if the baseline measurements were completed without any apnoeas observed. The infant car seat can be set up in the hospital such that it is placed on a rigid surface at the same inclination angle at which the seat will be installed in the vehicle. The infant will then be secured in the car seat following the manufacturer guidelines. The researchers must ensure that the infant is properly secured such that he/she can maintain good posture without his/her head being positioned in such a way that the airway is restricted. Once the infant is secured in the car seat, measurements of the infant's cardiorespiratory response will be obtained for 30 minutes.

Test 2: In-vehicle Measurements

If Test 1 was completed without any apnoeas observed (see Figure 10), the infant and pulse oximeter may be moved to the vehicle. The accelerometers used to instrument the infant car seat can then be connected to the data acquisitioning system located within the vehicle. A check should be performed to ensure that all the equipment and sensors are functioning as expected. The researchers will then proceed to drive along the mission profile. The same driver should be used for all tests to limit variability in vehicle speed due to different driving styles. The driver must strictly adhere to the speed limits of the areas being tested. If the mission profile is completed without any apnoeas observed and the parents of the infant select this option, the researchers may proceed along the route selected to the home of the infant.

Procedure if an Apnoea is Observed

Certain criteria have been identified to indicate if the infant is experiencing an apnoea and the health of the infant is thus compromised. These criteria are listed in Table 7. The following procedure should be followed in the event of an apnoea being noted during testing:

1. Confirm that the measurements are correct by making use of the additional pulse oximeter system (monitor for 20s). This is done to ensure that the reading is not related to a fault in the equipment or the sensor losing contact with the infant.
2. If the measurements are correct, reposition the infant to correct a possible incorrect posture (defined as the head of the infant being in a position such that the airway can become restricted). Monitor for 20s.
3. If the response does not resolve, stimulate the infant, and monitor for 20s

If stimulating the infant (step 3) does not resolve the apnoea observed, the steps listed below will need to be performed (depending on whether the infant is involved in the baseline test, test 1 or test 2).

Apnoea During Baseline Tests and Test 1: Static Infant Car Seat

4. Inform a medical practitioner of the response of the infant.
5. Proceed to contact the paediatrician of the infant.

Apnoea During Test 2: In-vehicle tests

6. Drive to hospital that is in association with the paediatrician selected by the parents in the informed consent document (see Appendix D)
7. Inform the paediatrician of the apnoea observed

4.4 Conclusion

Multiple factors need to be accounted for when developing a method for a study involving infants as participants. Many of these important factors have been discussed in this section, including the criteria that may be implemented to recruit a minimum of 30 healthy, term infants. The multi-axis vibration input to the infant and resulting change in posture in the sagittal plane and change in cardiorespiratory measurements have been identified as the variables of interest for a study investigating the response of infants to multi-axis vibration associated with suburban driving. The procedures associated with different phases of the study, namely: obtaining ethical clearance, recruiting participants as well as testing have been documented. It has also been advised that an opinion poll be used to gauge the interest of prospective parents to participate in the study to determine whether the study is feasible.

In order to remain within the timeframe of a one-year Masters' study and due to the delays encountered with obtaining ethical approval, and challenges encountered with participation in the opinion poll and recruitment of participants, the researcher was not able to perform tests including infants as participants. Several critical aspects that are related to the vibration input to the infant car seats and which may influence the response of infants to WBV associated with vehicle travel have, however, been identified. These aspects include the mission profile selected for testing, as well as variations in the testing conditions such as vehicle speed and the number of occupants within the test vehicle. The transmissibility of the infant car seat over the selected mission profile also needs to be investigated. These aspects are described in greater detail in Chapter 5 and Chapter 6.

Chapter 5: Vibration Input to Infant

The focus of this chapter is to quantify the multi-axis vibrations to the infant (secondary aim of the study) and considering aspects that may influence these vibrations. Possible influencing aspects include the mission profile and variations in testing conditions - variations in vehicle speed due to driver and environmental factors and the number of passengers within the vehicle.

5.1 Materials and Methods for Characterisation of Vibration Input to Infant

The following section will document the materials and methods used to measure the vibration input to the infant. The vehicle and infant car seat setups referred to here are as discussed in sections 4.2.1 and 4.2.2 respectively.

5.1.1 Test Protocol

Preliminary tests were performed during which the instrumented infant car seat was placed within the instrumented test vehicle and driven along the mission profile identified for the study. A total of 15 test runs were performed. No mass was placed within the car seat during testing, as there is no information available regarding the apparent mass of new-born infants. The test driver was instructed to drive according to the speed- and traffic limitations of the area. Separate measurements were recorded from the participating hospital to the turnaround point, and from the turnaround point back to the participating hospital to limit file size and facilitate post-processing of data.

5.1.2 Estimation of Acceleration at Point of Interest

Two sets consisting of three triaxial accelerometers were used to capture the response of the vehicle sprung mass and the infant car seat respectively, as can be seen in Figure 6 and Figure 7. Equations (1) to (6) were then used to relate the accelerations measured on different points of the vehicle body and the infant car seat to the acceleration at their respective Points of Interest (POI). Equations (1) to (3) were used to estimate the rotational accelerations of the vehicle sprung mass and the infant car seat, and thus also the rotational accelerations of their respective POIs. The translational accelerations of the POI of the vehicle seat (POI_{VS}) and the infant car seat (POI_{ICS}) were calculated using Equations (4) to (6). The distances (d_x, d_y, d_z)

used to locate the POI relative to A_0, as well as the distances (D_x, D_y) used to locate the accelerometers A_1 and A_2 relative to accelerometer A_0, are provided in Table 12.

Table 12: Position measurements used to estimate POIs vibrational response

	D_x	D_y	d_x	d_y	d_z
POI_{VS}	1.602m	0.805m	1.602m	0.190m	0.3945m
POI_{ICS}	0.329m	0.1775m	0.1645m	0.0887m	0.160m

It must be mentioned that, in using Equations (1) to (6) to estimate the accelerations of the POIs of the vehicle seat and the infant car seat, it is assumed that the POIs and the locations where the accelerometers are secured form part of the same rigid body. This assumption is reasonable for the vehicle seat, as the frames of the seats are securely bolted to the vehicle floor, and the accelerometers $A_{v,0}$ to $A_{v,2}$ were secured to these seat frames during testing. The base and chair-section of the infant car seat do not form a perfectly rigid connection, and small relative motions are possible between the two components. However, once the infant car seat was secured in the test vehicle, these relative motions were reduced.

Unless stated otherwise, acceleration data were not weighted with weighting curves stipulated in BS 6841(1987), as these weighting curves were created for adult participants who most likely have different responses compared to infants and children. Acceleration data were, however, weighted with BS 6841 (1987) to allow for the comparison with available literature on the difference thresholds of adults for the investigation presented in section 5.3.2. Frequency domain techniques were used when signals were weighted.

5.2 Mission Profile

An out-and-back route was selected for the mission profile to ensure that participants will be exposed to the same events at different times during testing. The reasoning behind the double exposure is to assess whether the observed responses may be associated with the time spent travelling rather than the vibrational exposure from a specific event. Certain events of interest have been identified that are associated with typical vehicle travel which are expected to have a high probability of resulting in a change in posture or cardiorespiratory response of the infant. These events include speed bumps, stop streets and inclined road surfaces.

The pitch associated with travel over a speed bump may result in the back of the infant's head losing contact with the headrest of the infant car seat, resulting in the chin falling towards the chest and thus a change in posture. For a rear-facing infant car seat, the longitudinal acceleration encountered during the initial acceleration from a stop street coupled with the weak muscular strength of a new-born infant's neck may again result in a change in posture. When travelling along a steep incline, the rear-facing infant will already be in a compromised position, with the head of the infant naturally tending downwards under gravitational pull. Any vibration inputs may therefore further diminish the chances of the infant's posture remaining in a favourable state.

5.2.1 Mission Profile Selected

The mission profile was selected such that it includes the events of interest, while providing a range of vibrational inputs to test participants. The mission profile was divided into different sections that correspond to different events of interest, as can be viewed in Figure 11. The mission profile has an approximately distance of 6km from the participating hospital to the turnaround point, and an approximate total distance of 12km out-and-back.

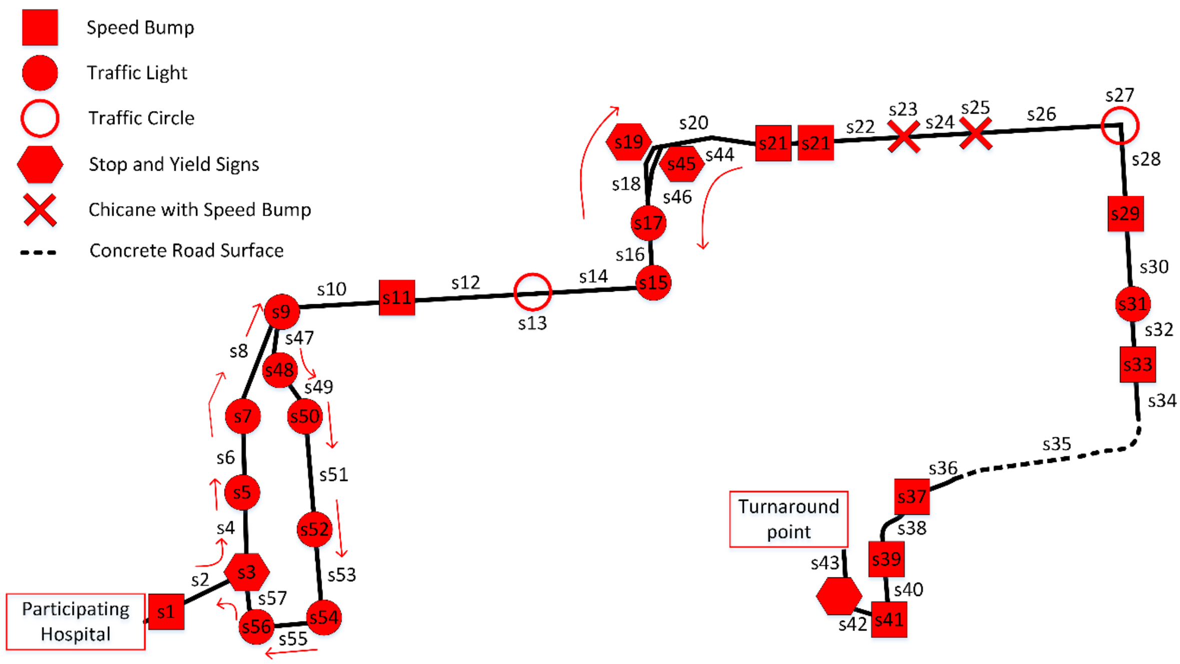

Figure 11: Mission profile selected for the study, including definition of the sections associated with different events

A summary of the distinct events encountered along the mission profile is presented in Table 13. All sections that have not been specified in this table are tar road sections without discrete events.

Table 13: Summary of distinct events encountered along mission profile

Event	**Associated sections**
Speed bump	s1, s11, s21, s29, s33, s37, s39, s41
Traffic light	s5, s7, s9, s15, s17, s31, s48, s50, s52, s54, s56
Traffic circle	s13, s27
Stop and yield signs	s3, s19, s45
Chicane with speed bump	s23, s25
Concrete road surface	s35

5.2.2 Characterisation of Mission Profile

As part of the characterisation of the mission profile, the frequency content of the measured vibration input to the infant through the system consisting of vehicle seat and infant car seat was assessed. This was done by evaluating the median PSD of the accelerations estimated at the interface between the infant and the seat, or POI_{ICS}, for the 15 test runs. These median PSDs can be seen in Figure 12 and Figure 13. From these figures it is evident that both the vertical acceleration as well as pitch have the highest energy content at frequencies of 2.1 Hz. This peak in energy content is likely related to the sprung mass natural frequency of the test vehicle. The energy content at higher frequencies (> 60 Hz) is lower for in-vehicle measurements in the three translational directions whereas the opposite is observed for the three rotational directions. All unweighted frequency data are displayed up to 100 Hz, which is the range of the accelerometers used to capture data. This is done as the sensitivity of infants to vibration frequency is still unknown, and therefore no frequency data may be disregarded.

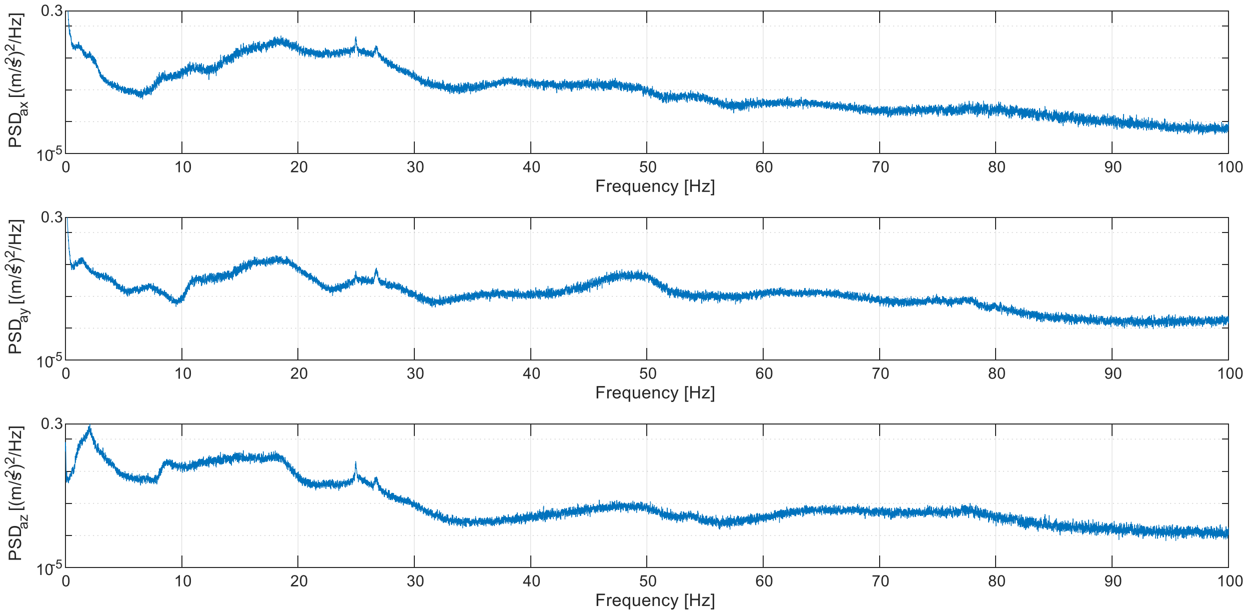

Figure 12: PSD of the longitudinal (Top), lateral (Middle) and vertical (Bottom) acceleration at POI_{ICS}

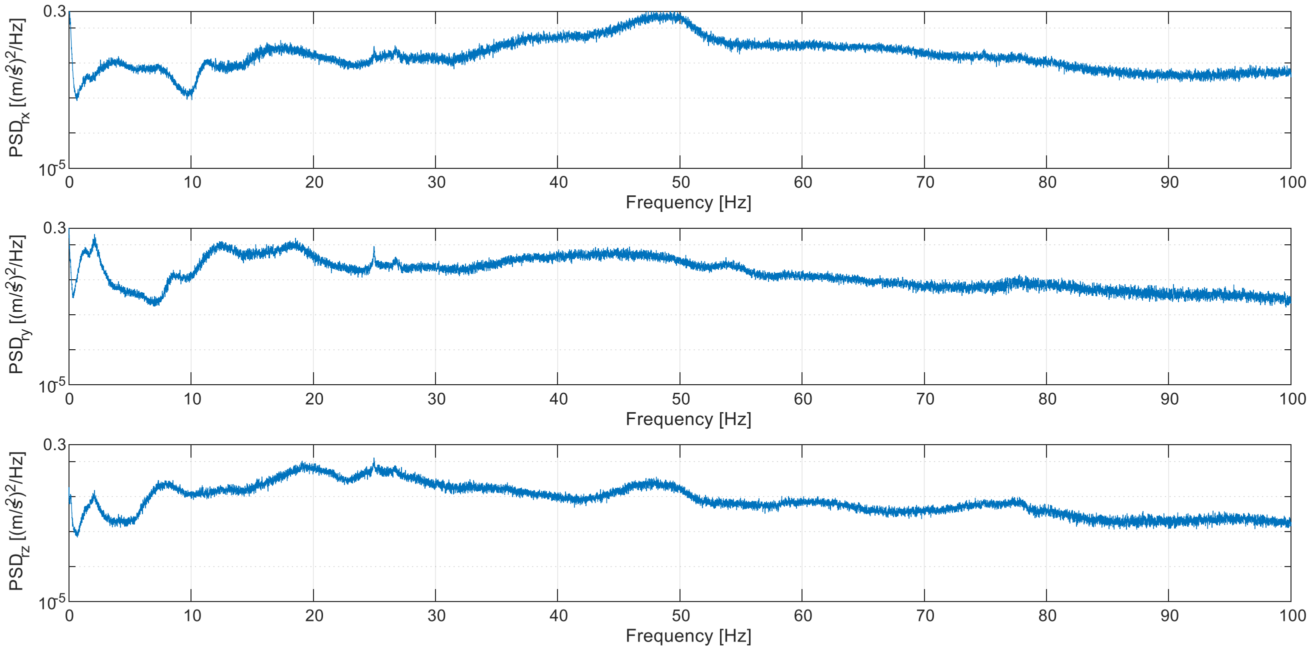

Figure 13: PSD of the roll (Top), pitch (Middle) and yaw (Bottom) at POI_{ICS}

As was mentioned in section 5.2.1, the mission profile was divided into sections corresponding to different events encountered along the route. The vibration input to the infant was estimated for each of the sections along the mission profile considering the acceleration at the POI_{ICS}. The BS 6841 (1987) frequency weighted RMS acceleration of the POI_{ICS} for each of the translational and rotational directions at each section of the mission profile are displayed in Figure 14 and Figure 15. The accelerations were weighted to enable the comparison to literature reporting the difference thresholds of adult vehicle occupants, described in detail in section 5.3.2. The boxplots were created from the weighted RMS accelerations of the 15 different test runs performed from the participating hospital to the turnaround point. The RMS metrics were used as, although one would expect CF values greater than 6 for general in-vehicle testing, it was found that most of the weighted measurements displayed CF values less than 6.

Type of road section	a_x	a_y	a_z	r_x	r_y	r_z
Speed bump	0.83	9.17	10.00	0.00	7.50	5.00
Traffic light	23.33	10.00	30.00	13.33	26.67	23.33
Traffic circle	0.00	0.00	33.33	0.00	6.67	0.00
Stop and yield signs	16.67	16.67	60.00	26.67	16.67	50.00
Chicane with speed bump	0.00	6.67	33.33	16.67	3.33	20.00
Concrete road surface	0.00	0.00	33.33	13.33	0.00	13.33
Tar road surface	5.15	1.52	19.09	9.09	13.64	20.00

The largest RMS acceleration was associated with the vertical acceleration measured on the rough concrete road (s35), and the median RMS vertical acceleration of 1.17 m/s^2 can be classified as being "*uncomfortable*" according to BS 6841 (1987). The data also clearly points out the higher RMS pitch accelerations that were associated with travelling over speed bumps along the test route. As can be expected, the yaw accelerations observed during normal suburban driving conditions was limited, compared to other acceleration directions.

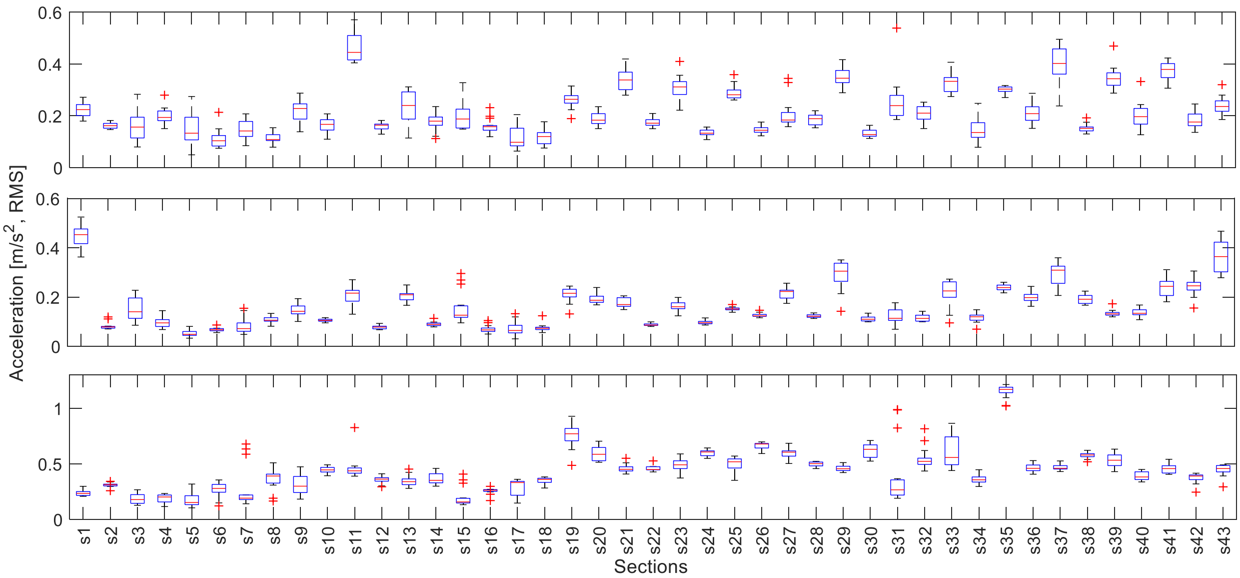

Figure 14: Weighted longitudinal (Top), lateral (Middle) and vertical (Bottom) accelerations estimated at POI_{ICS}

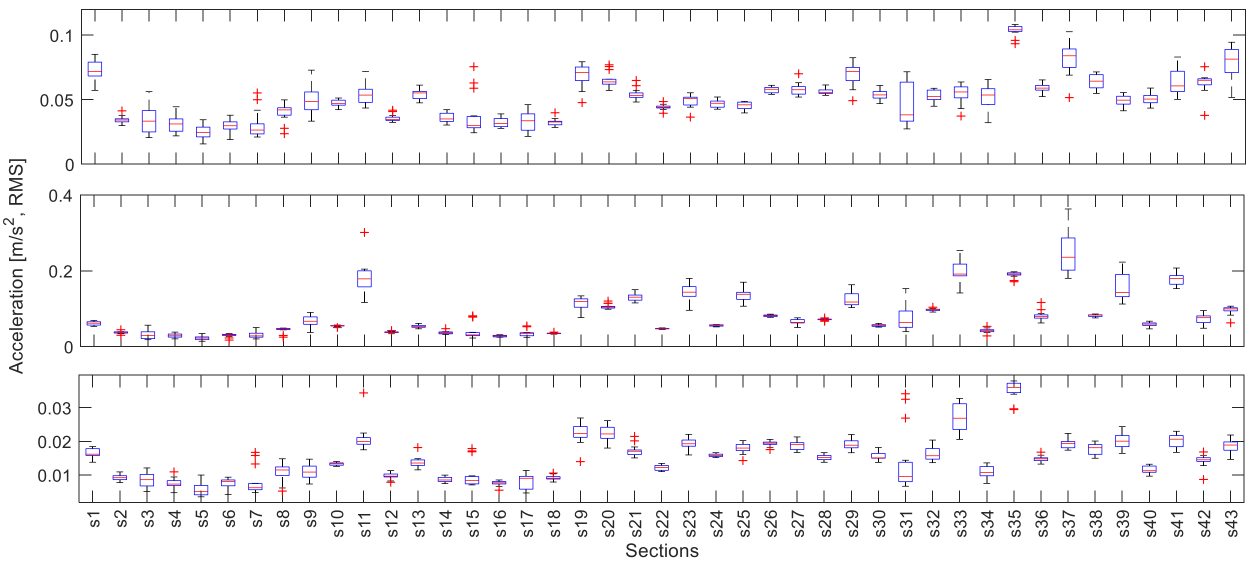

Figure 15: Weighted roll (Top), pitch (Middle) and yaw (Bottom) accelerations estimated at POI_{ICS}

It is clear from the evaluation of the PSDs as well as the RMS accelerations at POI_{ICS} that the selected mission profile provides a range of vibration inputs to the infant that will be seated in an infant car seat. It can also be seen that the different events encountered along the mission profile would provide different vibration inputs to the infants in each of the vibration directions of interest. The variation of the RMS accelerations between different sections, however, also serves as proof that the assumption of stationarity for the entire mission profile will most likely be violated.

5.3 Effect of Vehicle Speed and Seating Configuration on Measured Vibration

The mission profile was selected such that testing may take place under typical suburban driving conditions on a public road, to provide realistic vibration inputs to the infants. The use of a public road, however, implies that the speed of the vehicle will be governed by road rules and regulations, as well as traffic conditions. The effect of traffic conditions is seen by the variation in testing times from 12 to 17.5 minutes for tests performed from the participating hospital to the turnaround point. This will certainly result in variations in vehicle speeds between different tests. The test vehicle can accommodate a total of eight occupants, including the researchers and parents of the infant. The number of occupants may therefore vary between tests. These variations in testing conditions may affect the vibrational response of the vehicle and thus the vibration transferred to the infant. This section will investigate the effect of vehicle speed and seating conditions on the vibrational response of the vehicle and, subsequently, the effect on the vibration input to infants.

5.3.1 Effect of Vehicle Speed and Seating Configuration on Vehicle Vibrational Response

Prior to any testing commencing, the researcher identified the vehicle speed and the number of occupants within the vehicle as factors that may influence the vibrational response of the vehicle body, and thus the vibration transferred to the infants during testing. Tests were carried out at Gerotek Test Facilities (ARMSCOR, 2016) using the instrumented test vehicle to determine the effect of variations in vehicle speed and the seating configuration within the test vehicle on the vibration input to the infant car seat. The tests were carried out at the test facilities to limit variations in vehicle speed due to varying traffic conditions. Greater control could also be exercised by the test driver to maintain a constant speed during each of the tests. Two speeds (Sx) and at least two different seating configurations (Cx) were tested over two different road inputs, namely Belgian paving and a speed bump. A summary of the tests that were conducted can be viewed in Table 14. A total of five runs were performed for each of the tests. No infant car seat was included in the vehicle. The acceleration input to the seat that would be designated for the infant car seat was estimated using equations (1) to (6).

Table 14: Summary of different tests performed at Gerotek Test Facilities

	Different seating configurations			**Different vehicle speeds**	
	C_1	**C_2**	**C_3**	**S_1**	**S_2**
Belgian paving	3 people + 50kg weight	8 people	2 people	10km/h	20km/h
Speed bump	N.A.	8 people	2 people	5km/h	10km/h

The unweighted RMS of the estimated vibration input to the infant car seat was calculated for each test run in each of the three translational and three rotational directions. The estimated vertical RMS vibration input to the infant car seat can be viewed in Figure 16 for tests performed over the Belgian paving and Figure 17 for tests performed over a speed bump.

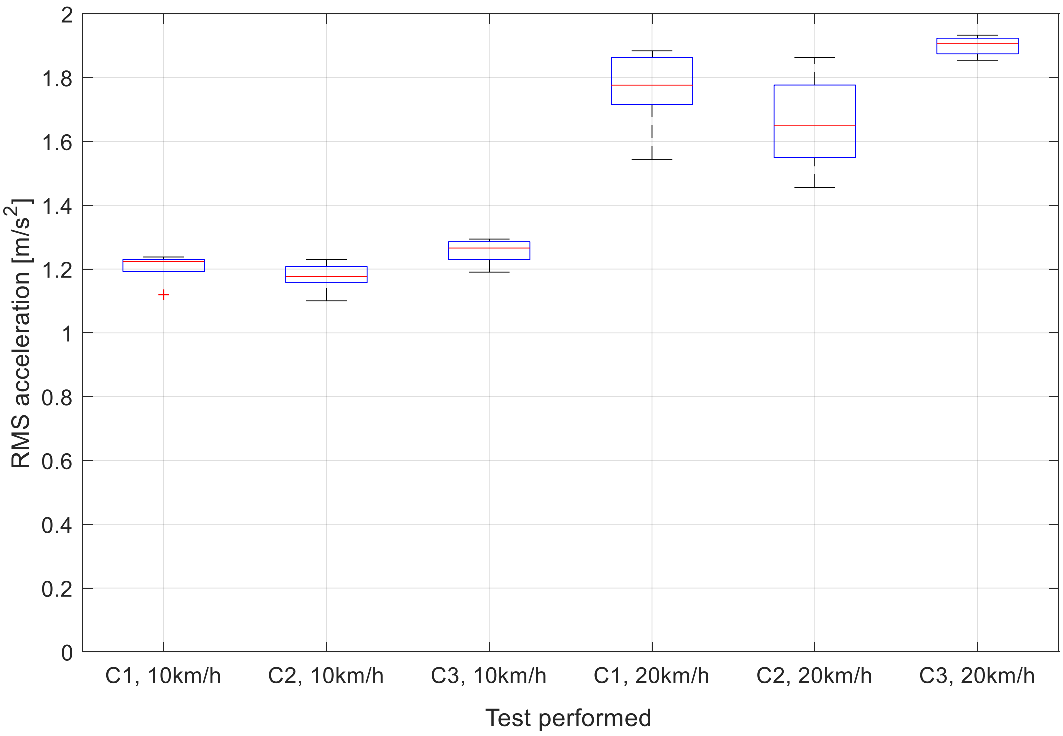

Figure 16: Boxplot of vertical (a_z) acceleration for each of the 6 different tests performed on Belgian paving

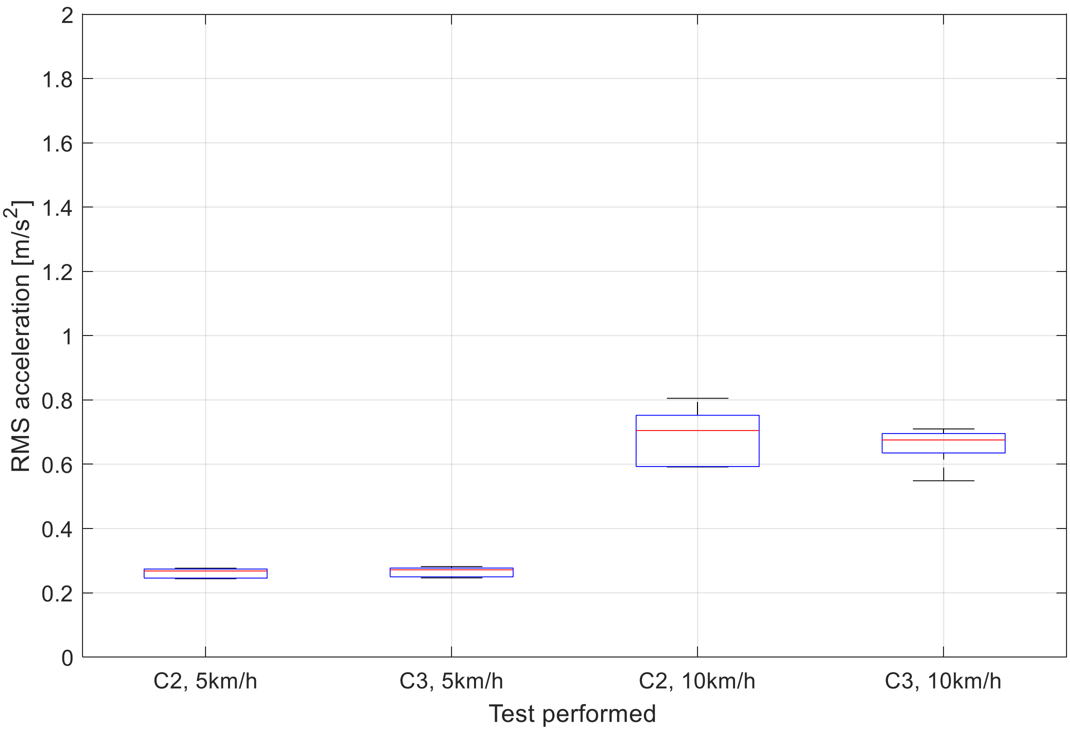

Figure 17: Boxplot of vertical (a_z) acceleration for each of the 4 different tests performed over a speed bump

Analyses were performed to determine whether the RMS acceleration in any of the translational or rotational directions measured for the groups tested (seating configurations and vehicle speeds) display statistically significant differences along the two road inputs. A Friedman test was used when three groups were compared, and a Wilcoxon Signed Rank test if two groups were compared. In addition to the Friedman tests, post hoc analysis Bonferoni adjustments were performed if any statistically significant differences existed between the three groups. These pairwise Bonferoni comparisons were used to identify the groups with the statistically significant differences. The null hypothesis, which states that the RMS vibration inputs for all the different groups tested are the same, was tested against the alternative hypothesis that they are not all the same. Tests were conducted at a 5% significance level ($\alpha = 0.05$), and the resultant *p*-values are displayed in Table 15 and Table 16 and for tests performed over the Belgian paving and speed bump, respectively.

Table 15: Friedman (with post hoc analysis Bonferoni adjustments) and Wilcoxon Signed Rank test results for Belgian paving (p-value < 0.05: significant difference at 5% level)*

	Test for variations in numbers of occupants at 10km/h				**Test for variations in numbers of occupants at 20km/h**				**Test for variations in vehicle speed for each seating configuration**		
	Post hoc analysis Bonferoni adjustment			**Friedman test**	**Post hoc analysis Bonferoni adjustment**			**Friedman test**	**Wilcoxon signed rank test**		
	C1 - C2	**C1 - C3**	**C2 - C3**	***p*-value**	**C1 - C2**	**C1 - C3**	**C2 - C3**	***p*-value**	**10 - 20 km/h C1**	**10 - 20 km/h C2**	**10 - 20 km/h C3**
a_x				0,819				0,074	0,043*	0,043*	0,043*
a_y	0,013 *	1	0,173	0,015*				0,165	0,043*	0,043*	0,043*
a_z	0,173	1	0,013 *	0,015*	1	0,173	0,013 *	0,015*	0,043*	0,043*	0,043*
r_x	0,013 *	1	0,173	0,015*				0,074	0,043*	0,043*	0,043*
r_y				0,074				0,449	0,043*	0,043*	0,043*
r_z	0,013 *	1	0,173	0,015*				0,074	0,043*	0,043*	0,043*

The results from Table 15 indicate that a variation in vehicle speed results in a statistically significant (*p*-value < 0.05) difference in RMS acceleration in each of the translational and rotational directions for each seating configuration tested along the Belgian paving. From Table 16, it can be seen that a variation in vehicle speed along the speed bump results in statistically significant difference between the RMS accelerations measured along each of the translational and rotational directions for a vehicle containing only two occupants, or seating configuration 3. A fully loaded test vehicle (seating configuration 2) only displays significant differences between the measured vibration in the longitudinal, vertical and pitch directions while travelling over a speed bump. This is likely due to the significant increase in vehicle sprung mass, making it less responsive to vibration inputs.

Table 16: Wilcoxon Signed Rank test results for Speed bump (p-value < 0.05: significant difference at 5% level)*

Seating config.	**C_2-C_3**	**C_2-C_3**	**C_2**	**C3**
Speed	**5km/h**	**10km/h**	**5-10km/h**	**5-10km/h**
a_x	0,5	0,686	0,043*	0,043*
a_y	0,043*	0,5	0,08	0,043*
a_z	0,686	0,345	0,043*	0,043*
r_x	0,5	0,225	0,5	0,043*
r_y	0,893	0,225	0,043*	0,043*
r_z	0,5	0,08	0,225	0,043*

Some statistically significant differences were observed for a variation in seating configuration for tests performed at 10 and 20km/h along the Belgian paving (p-values < 0.05 for the post hoc Bonferoni adjustment), as well as at 5km/h for the speed bump. These differences may be a result of variations in speed encountered during these tests, which were intended to be performed at constant speed, however, variations were still present due to human error.

The investigation presented in this section indicates that the number of occupants within the test vehicle has a statistically significant influence on the vibrational response of the vehicle body for certain circumstances, however, the effects observed may be a result of flaws present in the tests, i.e. speed control. The speed of the vehicle does, however, have a statistically significant influence on the vibrational response of the vehicle body under most circumstances, and it is therefore advised that the effect of vehicle speed on the vibration inputs to infants be investigated further.

5.3.2 Effect of Vehicle Speed on Vibration Inputs to Infants

The results from section 5.3.1 have indicated that vehicle speed influences the vibrational response of the vehicle body. In Figure 14 and Figure 15, it can also be observed that some sections of the mission profile have larger Inter Quartile Ranges (IQR), which is defined as

$$IQR = 75^{th} percentile - 25^{th} percentile = Q_3 - Q_1 \tag{14}$$

It is assumed that these variations of the weighted RMS accelerations are a result of the variation in vehicle speed between different test runs performed. A measure, namely, the relative difference between the 75th and 25th percentiles was defined as

$$Relative\ difference\ [\%] = \frac{Q_3 - Q_1}{Q_1} \cdot 100 \tag{15}$$

to serve as a measure of the variability of the weighted RMS acceleration between different test runs. The relative differences calculated for each of the sections of the mission profile in each of the translational and rotational directions of interest can be viewed in Figure 18. The accelerations measured in the longitudinal direction displayed the largest relative differences for the largest number of road sections. Again, this is likely due to the variations in vehicle speed between different tests.

A study conducted by Gräbe (2017) investigated the relative difference threshold of adult vehicle occupants by considering the weighted vertical accelerations on the seat of the test vehicle. Due to a lack of additional relevant literature, the relative difference obtained for the vertical direction was compared to the reported vertical relative difference thresholds of adult vehicle occupants. The results displayed in Figure 18 indicate that 24 of 43 (56%) of the sections encountered along the mission profile have relative differences greater than the relative difference threshold of the 75th percentile adult vehicle occupant for a smooth road input (13.18%) and a rough road input (12.55%) reported by Gräbe (2017). This means that, for 56% of the mission profile, an adult occupant will have a 79.4% chance of correctly identifying the larger of the vibration exposures between two different test runs. Although the adults will be able to perceive these differences, the findings from a recent study by Jooste (2018) suggest that these differences in vibration exposure will not affect the cardiovascular response of adult occupants. Whether these differences in vibration stimuli will result in different postural and/or cardiorespiratory responses of infants remains to be investigated.

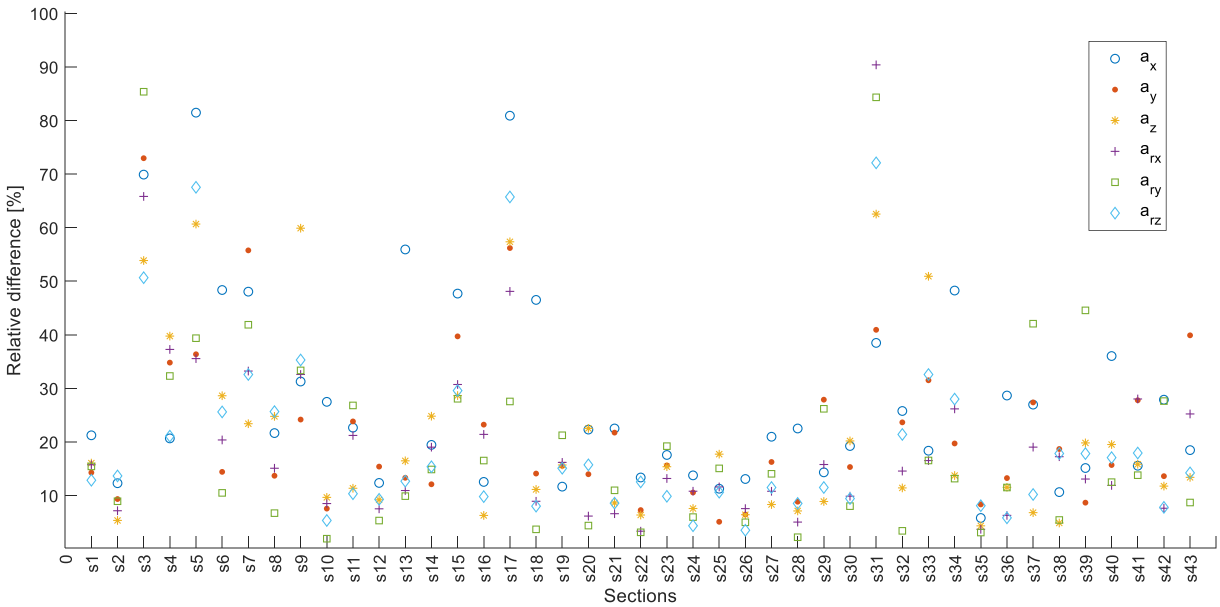

Figure 18: Relative difference between the 25th and 75th percentile weighted acceleration for the sections in the mission profile in all translational and rotational directions

5.4 Conclusion

A possible mission profile was identified and characterised for a study investigating the response of infants to vehicle vibration. The effect of the variation in vehicle speed and the number of occupants in the vehicle on the vibrational response of the vehicle body was investigated. It was found that the variation in vehicle speed has a statistically significant influence on the vibrational response of the vehicle body, and that the resultant variations in vibration input to the infants will likely be detectable by adult occupants, although it may not affect their cardiovascular responses. Whether the variations in vibration input will be detectable by infants and whether it will affect their cardiorespiratory responses remains to be investigated.

Chapter 6: Transmissibility of Infant Car Seat

In order to understand the role of the infant car seat in the multi-axis vibration transferred to the infant, the transmissibility of multi-axis vibration between the vehicle seat and the infant car seat was determined. This provides valuable information regarding the amplification and attenuation of vibration to the infant in different vibrational directions, and the specific frequencies at which this occurs. It is possible that this information can be used to detect the vibration magnitudes, -directions and -frequencies that may have the largest effect on the posture of infants. When tests are performed that will include infants as participants, it will also be of great value if any changes in cardiorespiratory response or noteworthy events, that may lead to an apnoea, can be correlated with a specific event encountered along the mission profile or a specific vibration magnitude or -direction. If the vibration frequencies associated with the change in posture or noteworthy events can be identified and the vibrational response of the infant car seat at these frequencies investigated, infant car seats may be designed to better protect the infants from the vibration transferred at these frequencies.

6.1 Estimation of Vibration Transmissibility

The unweighted accelerations estimated at POI_{ICS} and POI_{VS} were used to approximate the transmissibility of the system consisting of the vehicle seat and infant car seat, as can be seen in Figure 19. The complex transfer function, modulus and phase were approximated using Equations (9) to (11) for each of the three translational and rotational directions of interest. The coherency of the transfer function between the output vibration (POI_{ICS}) and the input vibration (POI_{VS}) was estimated using Equation (12).

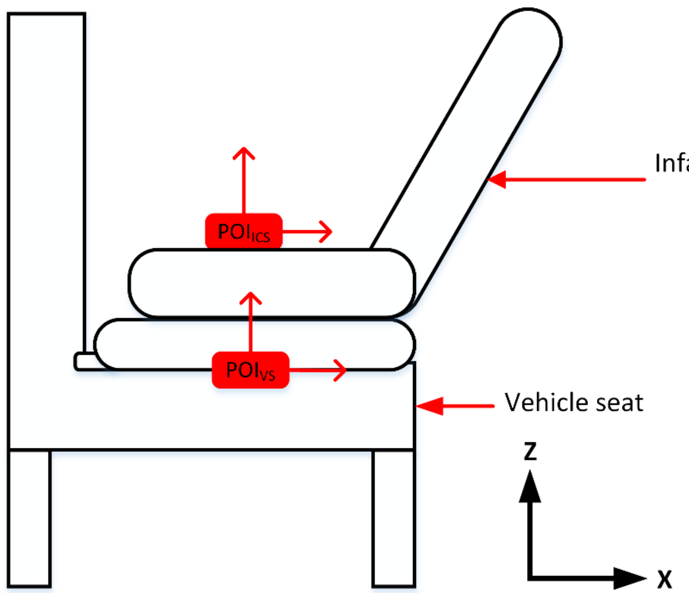

Figure 19: Approximation of the transfer function for the system consisting of the vehicle seat and infant car seat

When calculating the complex transfer function using Equation (9), an approximation of the PSD and cross-spectral density is required. The PSD of the acceleration measurement under question was estimated using Welch's averaged, modified periodogram method of spectral estimation that is a function from the Signal Processing Toolbox of MATLAB® R2018b. The measurement signal was divided into 8 segments, with 50% overlap between the segments. Each segment was windowed by making use of a Hamming window. A total of 1052100 discrete Fourier points was specified for the PSD of the full mission profile (corresponding to the number of data points of the longest test file), resulting in a frequency resolution of 0.00095Hz. The relationship between the input and output accelerations of the system under investigation was determined using the cross-spectral density function inherent to the Signal Processing Toolbox of MATLAB® R2018b. This function also makes use of Welch's averaged, modified periodogram method of spectral estimation, and therefore the cross-spectral densities were estimated with the same settings that were used to estimate the PSDs.

It must be mentioned that the method of approximating the accelerations of the POIs using Equations (1) to (6) does not account for the effects of the cushions of the vehicle seat or the infant car seat. In order to capture the effect of the compliant seats, vibration transducers such as seat pad accelerometers need to be placed on top of the seat cushions to measure the vibrational response at these surfaces. In the case of the infant car seat, an apparent mass with a biodynamic response similar to that of a new-born infant would also need to be secured within the seat. Currently, there is no information available on the apparent mass of new-born infants. For the current study, a SI-SO approach was followed to estimate the transfer of vibration between the vehicle seat and the infant car seat. The vehicle is however subject to multi-axis vibration, where the vibration in one direction at the vehicle seat may influence the vibration in multiple directions at the infant car seat. The results obtained from these analyses are therefore only an approximation of the transfer of vibration that occurs for a system consisting of a vehicle seat and infant car seat.

6.2 Transmissibility Estimated from Entire Mission Profile

The transmissibility of the system consisting of vehicle seat and infant car seat was calculated for each of the test runs performed, and in each of the translational and rotational directions. The median transfer function modulus, phase and coherency was established for the 15 test runs performed, as can be seen in Figure 20 and Figure 21. It is evident that the coherency, or measure of the linear relationship between input and output accelerations of the system, are low for the majority of frequencies. For the vertical direction, the coherency at frequencies lower than 10Hz is good (> 0.75). However, as the transfer modulus approaches its peak transmissibility of 3.45 at 14.96Hz, the coherency also decreases to below 0.5. This may indicate the presence of other vibrational directions influencing the vertical response measured at the POI_{ICS} for frequencies in the range 13-19Hz. The pitch measurements also display a significant peak in transfer function modulus at approximately 17Hz. This peak, again, is associated with low coherency values, making it more difficult to interpret the transfer function obtained from the in-vehicle measurements. A peak of 2.343 in the lateral acceleration transfer function can be viewed at a frequency of 1.4Hz, with a coherency value of 0.887. A peak of 4.067 in the longitudinal acceleration could also be seen at a frequency of 19.49Hz, with a coherency value of 0.661.

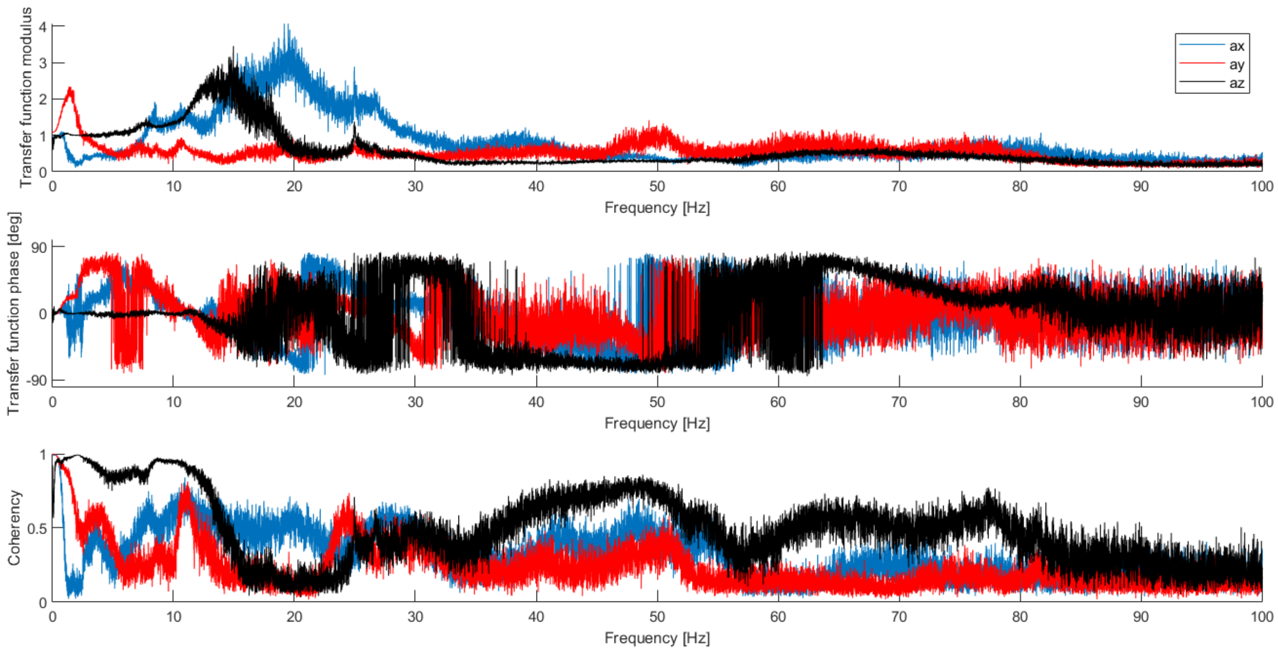

Figure 20: Median transfer function modulus (top), phase (middle) and coherency (bottom) for translational accelerations ax, ay and az measured along the entire mission profile

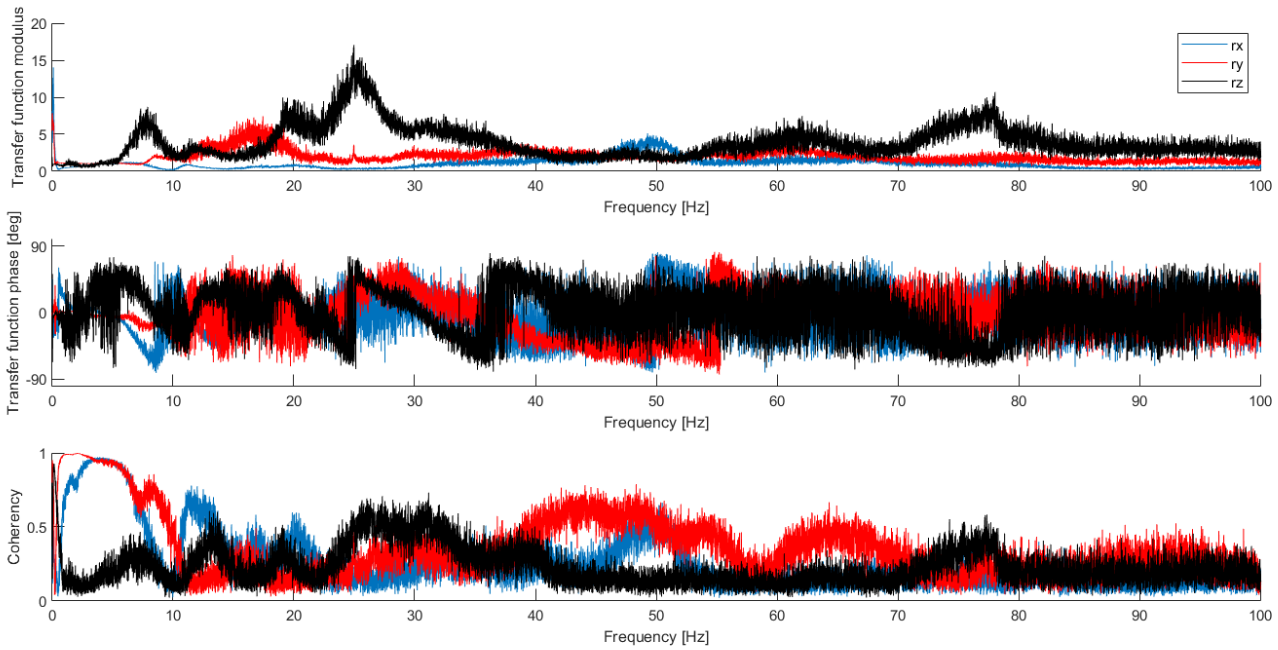

Figure 21: Median transfer function modulus (top), phase (middle) and coherency (bottom) for rotational accelerations rx, ry and rz measured along the entire mission profile

6.3 Evaluation of Certain Road Sections

One of the assumptions that are made when estimating the PSD of measurement data by making use of Welch's method is that the measurement data is stationary in nature, i.e. the mean and variance of the data does not change over time. However, when considering the different events encountered along the mission profile and thus the different vibration inputs to the vehicle and infant car seat, it is evident that analyses performed for the full mission profile will violate this assumption. The violation of the assumption of stationarity can also be seen in the variation of the median RMS acceleration between different sections of the mission profile, as is shown in Figure 14 and Figure 15. It was therefore decided to evaluate the transmissibilities associated with different sections of the mission profile to increase the likelihood of the stationarity of the data. A total of 10000 discrete Fourier points was specified for the PSDs, resulting in a frequency resolution of 0.1Hz. Although the measurement time associated with each section was different, a constant number of points was used for the different sections to ensure the same frequency resolution for better comparability.

The sections selected for the investigation included a speed bump (s11), smooth tar road (s26) as well as rough concrete road (s35). In addition to the investigation of the effect of the stationarity of the data, this evaluation was used to compare the transfer functions estimated for each section to that which is estimated for the entire route. The variability of the transfer functions calculated between the 15 different test runs is captured here as the IQR of the test runs. The resultant moduli, phases and coherencies of the transfer functions calculated in each of the translational and rotational directions for each of the sections of interest are displayed in Figure 22 and Figure 23.

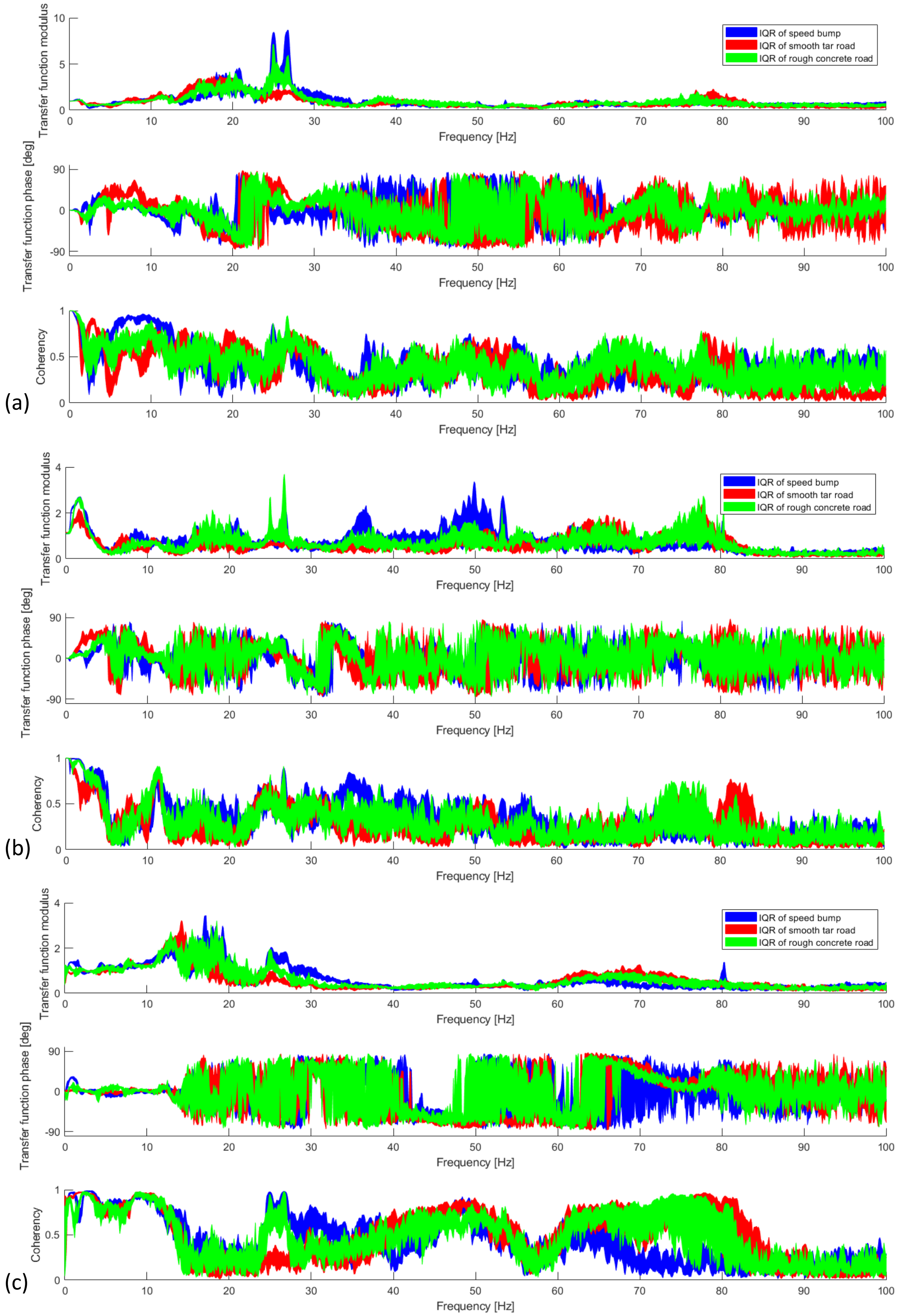

Figure 22: a_x (a), a_y (b) and a_z (c) - IQR of the transfer function modulus (top), phase (middle) and coherency (bottom) for for sections s11, s26 and s35 of the mission profile

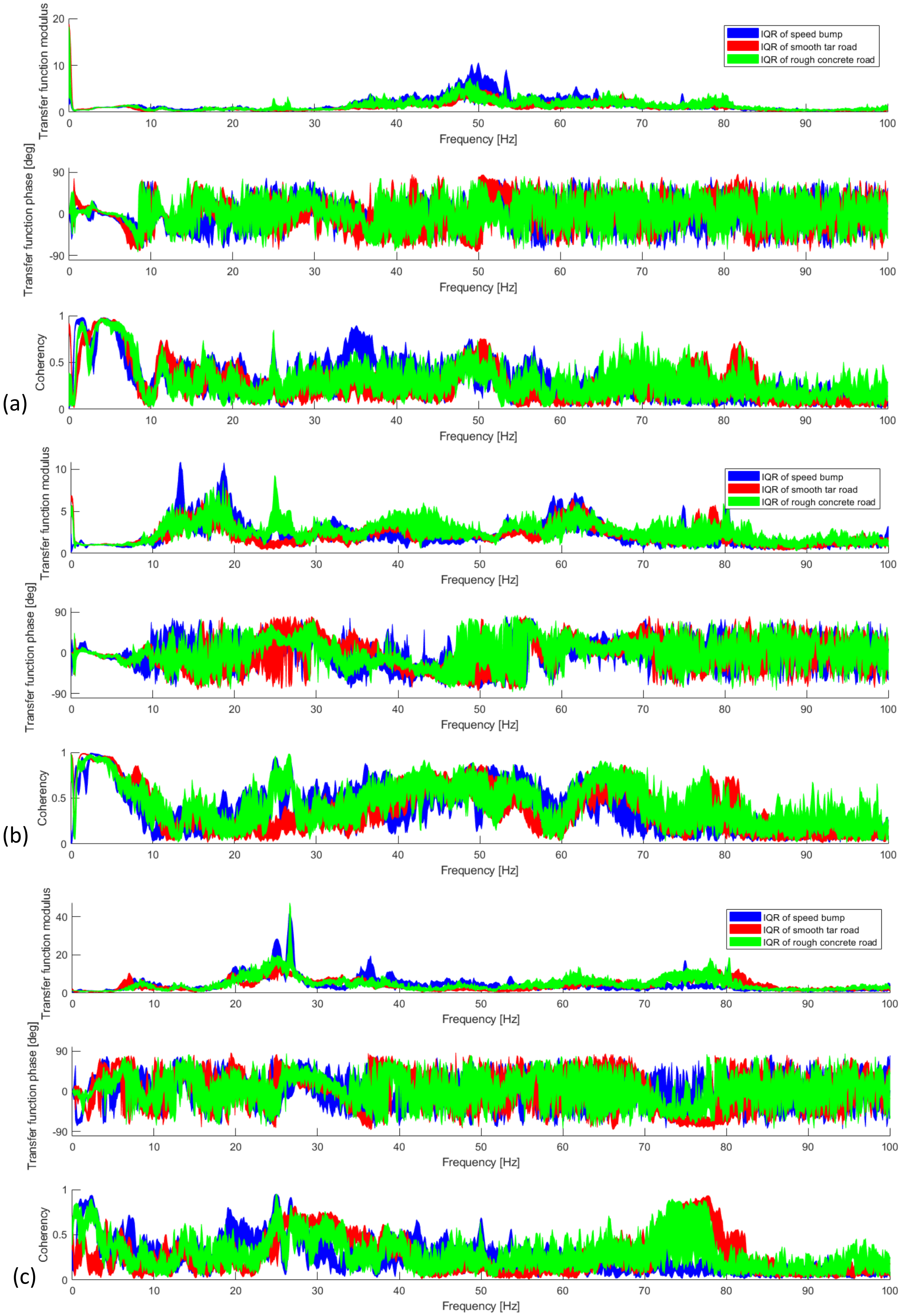

Figure 23: r_x (a), r_y (b) and r_z (c) - IQR of the transfer function modulus (top), phase (middle) and coherency (bottom) for for sections s11, s26 and s35 of the mission profile

In general, some improvements can be seen for the coherency values at lower frequency values (< 10Hz) when the transfer functions are estimated for different sections of the mission profile. It is interesting to note that the transfer functions obtained for the speed bump and rough concrete road surface follow similar trends for each of the translational and rotational directions. Again, the modulus of the vertical transfer functions display peaks (> 2) in the frequency range 12.9 - 19.2Hz. The coherency values are, however, also decreasing within this region, hence, it is uncertain how representative this transfer function is of the actual transfer of vibrations from the vehicle seat to the infant car seat. Peaks in the transfer function modulus (> 1.5) are also observed for the speed bump at frequencies of 25Hz and 26.6Hz for the vertical and pitch directions, as well as the rough concrete road at frequencies of 25Hz for the vertical direction and 26.6Hz for the pitch direction. All of these peaks are associated with good coherency values (> 0.725). It is seen that, although the transfer functions obtained for sections of the mission profile may follow similar trends compared to the transfer functions obtained for the entire mission profile, the energy content of the sections are limited. The transfer functions associated with sections of the mission profile are therefore not generalisable to the entire mission profile. The IQR of the transfer functions however indicate limited variability between the 15 different test runs performed, thus indicating good repeatability of the results obtained for the sections.

6.4 General Discussion of Transmissibility Results

Substantial transmissibilities were observed for specific frequencies for each of the translational and rotational accelerations when transmissibilities were calculated for the full mission profile and for sections of the mission profile. Poor coherencies were, however, observed for many of these peak transmissibilities, making it difficult to interpret whether the transfer functions that have been calculated are representative. When comparing the coherency plots with the median PSDs shown in Figure 12 and Figure 13, one can see that many of the frequencies that are associated with low coherency values typically contain very low amounts of energy. The issue with determining transmissibilities from inputs that do not contain sufficient energy at all frequencies, as is often the case with real road data, has been discussed by Griffin (1990).

The simplified, SI-SO approach may also be responsible for some of the low coherencies observed, as cross-vibrational transfer effects are neglected with this approach. In an environment with substantial multi-axis vibration, it is likely that the vibration in one direction at the vehicle seat may affect the vibration in a different direction at the infant car seat. The manner in which the transfer functions are calculated using the SI-SO approach will not account for this cross-vibration transfer, and thus the linear relationship between the input and output for a specific vibration direction will be low, even if a peak in the transmissibility is observed due to the influence of other vibration directions of the input.

It was assumed that evaluating the transmissibility of sections of the mission profile would better meet the assumption of stationarity than evaluating the transmissibility of the full mission profile. However, this only resulted in a slight improvement in the coherency values associated with the transfer functions. No conclusions can be made whether the poor coherencies displayed are a result of the data being non-stationary or the SI-SO approach used to calculate the transmissibilities.

The vertical transmissibilities between the vehicle floor and the interface between the infant and the infant car seat reported by Giacomin (2000) indicate that the system consisting of infant, infant car seat and vehicle seat amplified vibration at frequencies of approximately 6Hz and 11Hz, and then again from 25Hz to 55Hz. Peak transmissibilities of 400% were observed at multiple frequencies between 40Hz and 55Hz. The mean vertical transmissibilities between the vehicle floor and interface between the infant and infant car seat reported by Giacomin and Gallo (2003) indicate amplification of vibration at approximately 8.5Hz, and attenuation of vibration at frequencies higher than 12Hz. The vertical transmissibility between the vehicle seat and interface between the infant and the infant car seat obtained for the full mission profile indicated vibration amplification from approximately 7Hz to 19Hz, with the peak transmissibility encountered at approximately 15Hz. This does not agree well with results reported by Giacomin (2000) or Giacomin and Gallo (2003), who also reported good coherency values for the vertical transmissibilities obtained. One possible cause for the disparity is the fact that infants were not included in the study, and therefore the transmissibilities were estimated for the interface between the infant and the infant car seat. Another dissimilarity between the current study and previous studies is the use of an ISOFIX infant car seat instead of a seatbelt fastened infant car seat, which provides a rigid connection to the vehicle seat frame. Thirdly, the researcher accounted for the relationship between the input and output acceleration measurements by making use of the cross-spectral density when calculating the transmissibilities, however, the studies by Giacomin (2000) and Giacomin and Gallo (2003) made use of PSDs, which may neglect the cross-axis vibration transfer effects. It is advised by Griffin (1990) to make use of the cross-spectral density rather than the PSD. Therefore, this method was used for the current study.

Better transmissibilities may also be obtained if the infant car seat is tested under laboratory conditions, where the vibration inputs to the infant car seat can be controlled closely and therefore ensured that the energy content of each frequency band of interest is sufficiently high. The inclusion of infants will, of course, also influence the transmissibilities obtained, as the dynamic response of the seat will then be captured at the seat interface and not estimated as has been done with the current method. The interaction between the infant body (in terms of resonance frequencies, etc.) and the infant car seat is also complex, and it is expected that this will also influence seat transmissibility.

6.5 Conclusion

The transmissibility of the infant car seat along the mission profile and sections of the mission profile was investigated. Although frequencies were identified where the vibration input to the infants are amplified by the vehicle seat-infant car seat system in each of the translational and rotational directions, the coherency values of these transfer functions make it challenging to interpret the results. The low coherency values are likely related to the low energy content of the mission profile at certain frequencies, as well as the cross-vibration transfer effects that are neglected in the SI-SO approach used to calculate the transfer functions. It is expected that different transmissibilities will be obtained once infants are included during testing.

Chapter 7: Conclusion

The primary aim of this study was to propose a method that can be used to investigate the effect of vehicle vibration on the posture and cardiorespiratory response of new-born infants. The secondary aim was to quantify the multi-axis vibration input to infants encountered under real driving conditions. The tertiary aim was to investigate the multi-axis transmissibility of infant car seats exposed to in-vehicle multi-axis vibration.

A holistic approach was developed to investigate the effect of vehicle vibration on the cardiorespiratory response of healthy, term infants. This included identifying aspects that may influence this response; including the vehicle environment in which the infant is situated, the multi-axis vibration transferred to the infant and posture changes that may result from the multi-axis vibration exposure. A thorough method was developed, which included identifying the equipment needed for the study and developing procedures for the recruitment- and testing of participants.

Critical aspects were identified which may influence the vibration input to an infant during testing. These aspects included the mission profile and the variation in vehicle speed between different tests. The mission profile was selected such that it included a range of different discrete events that would supply a range of vibration inputs to the infant and may result in a change in posture. The vehicle speed was also shown to influence the vibration input to the infant, and although these differences will be detectable by adult vehicle occupants, the question whether these differences will influence the response of infants remains to be investigated.

The multi-axis vibration transfer of an infant car seat subjected to the vibration encountered along the mission profile and sections of the mission profile was investigated using a SI-SO approach. Although distinct peaks in the transmissibilities could be observed for each of the vibration directions under investigation, the coherencies associated with the transfer functions were low for many of the frequencies under investigation. This is likely due to the low energy content of a large range of frequencies measured along the mission profile. This is, however, a problem inherent to in-field testing. The effect of the cross-transfer of vibration and the neglection of these effects in the SI-SO approach may also serve as an explanation to the low coherency values reported for the transfer functions that were obtained. It is, however, expected that these transmissibilities will change once infants are included during testing.

The findings from this study form an important basis for future studies that aim to investigate the effect of vehicle vibration on the postural and cardiorespiratory response of new-born infants. Once the relationship between posture, cardiorespiratory response and vibration input (magnitude, frequency and direction) has been established, the transmissibility of the infant car seat can be evaluated to identify any changes in design that are necessary.

Chapter 8: Recommendations for Future Work

The purpose of this study was to form the foundation for future research that aims to investigate the cardiorespiratory effect of vehicle vibration on healthy, term infants. Throughout the course of the study, certain aspects have been identified that need to be addressed in future research.

8.1 Future work

Determine multi-axis transfer functions using a MI-SO approach. Research by Qiu and Griffin (2004) showed that a MI-SO approach offered significant improvements in the coherencies of transfer functions compared to the SI-SO approach. It is therefore anticipated that the transfer functions obtained from a MI-SO approach will be more representative of the actual transfer of vibration that occurs between the vehicle seat and the infant car seat.

Determine multi-axis transfer functions for different infant car seats and/or different test vehicles. Another aspect that may be investigated is the variation in the transfer of vibration for different infant car seats, or the same infant car seat located in different vehicles. Such an investigation will shed light on the impact of the selected infant car seat and the selected vehicle on the vibration transfer. A comparison can also be performed between the vibration transfer of ISOFIX and seatbelt-fastened infant car seats.

Investigate the effect of vehicle vibration on the posture change and cardiorespiratory response of healthy, term infants. The aspiration of the researcher is that the work conducted in the current study be continued to include infants and investigate their postural and cardiorespiratory response to vehicle vibration. Such a study will not only add to the limited body of knowledge regarding the effect of vehicle vibration on the response of infants, but may also provide valuable information that may be applied to future designs of infant car seats or the development of procedures such as the ICSC to enhance the health of infants.

8.2 Administrative tasks

Opinion poll for a study including infants as participants. Although the current study conducted an opinion poll to determine the interest of prospective parents to allow their babies to participate in the overarching study, participation in the opinion poll posed a serious challenge. It is therefore recommended that the issues associated with participation in the opinion poll be identified, and the distribution of the opinion poll be managed better to enhance participation.

Feedback from prospective parents regarding the experimental design and proposed method. One of the aims of the opinion poll was to obtain feedback from prospective parents regarding the experimental design and proposed method for the study. Once this feedback has been obtained, it is recommended that the procedures associated with recruitment and testing be revisited with the feedback from the opinion poll to enhance participation in the study.

Time allocation for ethics applications. It is recommended that future investigations that aim to include infants as participants be familiar with the processes associated with obtaining ethical clearance, as well as the time associated with these applications, before commencing with the study. This time needs to be accounted for in the planning of the investigation.

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Appendix A: Ethical Approval

Faculty of EBIT

Faculty of Engineering, Built Environment and Information Technology

Fakulteit Ingenieurswese, Bou-omgewing en Inligtingtegnologie / Lefapha la Boetšenere, Tikologo ya Kago le Theknolotši ya Tshedimošo

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Reference number: EBIT/135/2018 25 January 2019

Ms M van der Westhuizen
Department Mechanical and Aeronautical Engineering
University of Pretoria
Pretoria
0028

Dear Ms Van der Westhuizen

FACULTY COMMITTEE FOR RESEARCH ETHICS AND INTEGRITY

Your recent application to the EBIT Research Ethics Committee refers.

Conditional approval is granted.

This means that the research project entitled "*Cardiorespiratory effect of vehicle vibration on healthy term infants*" is approved under the strict conditions indicated below. If these conditions are not met, approval is withdrawn automatically. The applicant is not required to submit an updated application.

Conditions for approval

- Conditional approval is granted by the EBIT Ethics Committee. Endorsement is required by the Faculty of Health Sciences Research Ethics Committee (FHSREC) as required by the Health Act. The applicant should apply to the FHSREC using their procedures, and may not commence with any aspects of the work that require ethics clearance before receiving such approval from the FHSREC.

Notes for the attention of the FHSREC

- The EBIT Ethics Committee is satisfied that this a carefully considered study. There are no specific ethical concerns that our committee wishes to bring to the attention of the FHSREC except the following. The EBIT Ethics Committee does not have the necessary expertise to comment on the inclusion of infants in the study and the relevant legal requirements, and will rely on the FHSREC to evaluate this aspect.

This approval does not imply that the researcher, student or lecturer is relieved of any accountability in terms of the Code of Ethics for Scholarly Activities of the University of Pretoria, or the Policy and Procedures for Responsible Research of the University of Pretoria. These documents are available on the website of the EBIT Ethics Committee.

If action is taken beyond the approved application, approval is withdrawn automatically.

According to the regulations, any relevant problem arising from the study or research methodology as well as any amendments or changes, must be brought to the attention of the EBIT Research Ethics Office.

The Committee must be notified on completion of the project.

The Committee wishes you every success with the research project.

Prof JJ Hanekom
Chair: Faculty Committee for Research Ethics and Integrity
FACULTY OF ENGINEERING, BUILT ENVIRONMENT AND INFORMATION TECHNOLOGY

Faculty of Engineering, Built Environment and Information Technology
Fakulteit Ingenieurswese, Bou-omgewing en Inligtingtegnologie / Lefapha la Boetšenere, Tikologo ya Kago le Theknolotši ya Tshedimošo

Reference number: EBIT/E5/2019 4 March 2019

Ms M van der Westhuizen
Department of Mechanical and Aeronautical Engineering
University of Pretoria
Pretoria
0028

Dear Ms Van der Westhuizen

FACULTY COMMITTEE FOR RESEARCH ETHICS AND INTEGRITY

Your recent application to the EBIT Research Ethics Committee refers.

Conditional approval is granted.

This means that the research project entitled "*Opinion poll for study: Cardiorespiratory effect of vehicle vibration on healthy term infants*" is approved under the strict conditions indicated below. If these conditions are not met, approval is withdrawn automatically. The applicant is not required to submit an updated application.

Conditions for approval

1) At Netcare Femina, permission is not only required from the hospital, but also from doctors in whose practice participants will be recruited and from the receptionists tasked to hand out such forms. Similar restrictions may apply to Midwives Exclusive. Conditional approval is given in order to obtain permission from Femina. However, only practices in hospitals where consent from the doctors and receptionists can be obtained may then be requested to distribute invitations. (With only permission from Femina/Midwifes Exclusive, invitations may be posted in public spaces that belong to the institution.)

2) The declaration submitted by the student is an HTML file that does not seem to contain the appropriate information. Kindly forward the correct declaration to the EBIT Ethics Office.

This approval does not imply that the researcher, student or lecturer is relieved of any accountability in terms of the Code of Ethics for Scholarly Activities of the University of Pretoria, or the Policy and Procedures for Responsible Research of the University of Pretoria. These documents are available on the website of the EBIT Ethics Committee.

If action is taken beyond the approved application, approval is withdrawn automatically.

According to the regulations, any relevant problem arising from the study or research methodology as well as any amendments or changes, must be brought to the attention of the EBIT Research Ethics Office.

The Committee must be notified on completion of the project.

The Committee wishes you every success with the research project.

Prof JJ Hanekom
Chair: Faculty Committee for Research Ethics and Integrity
FACULTY OF ENGINEERING, BUILT ENVIRONMENT AND INFORMATION TECHNOLOGY

Faculty of Health Sciences

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 03/14/2020.

8 April 2019

Approval Certificate
New Application

Ethics Reference No.: 84/2019
Title: Cardiorespiratory effect of vehicle vibration on healthy term infants

Dear Miss M van der Westhuizen

The **New Application** as supported by documents received between 2019-02-26 and 2019-03-27 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 2019-03-27.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year and needs to be renewed annually by 2020-04-08.
- Please remember to use your protocol number (84/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Dr R Sommers
MBChB MMed (Int) MPharmMed PhD
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

Research Ethics Committee
Room 4-60, Level 4, Tswelopele Building
University of Pretoria, Private Bag X323
Arcadia 0007, South Africa
Tel +27 (0)12 356 3084
Email deepeka.behari@up.ac.za
www.up.ac.za

Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

Participating Hospital

RESEARCH OPERATIONS COMMITTEE FINAL APPROVAL OF RESEARCH

Approval number: UNIV-2019-0008

Ms Moniqué van der Westhuizen

E mail: u13113462@tuks.co.za

Dear Ms Van der Westhuizen

RE: OPINION POLL FOR THE STUDY: CARDIORESPIRATORY EFFECT OF VEHICLE VIBRATION ON HEALTHY TERM INFANTS

The above-mentioned research was reviewed by the Research Operations Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at private Hospital, has been approved, subject to the following:

i) Research may now commence with this FINAL APPROVAL from the Committee.

ii) All information regarding the Company will be treated as legally privileged and confidential.

iii) The Company's name will not be mentioned without written consent from the Committee.

iv) All legal requirements regarding patient / participant's rights and confidentiality will be complied with.

v) All data extracted may only be used in an anonymised, aggregated format and for the purposes of this specific study as specified in the proposal. The data may under no circumstances be used for any other purpose whatsoever.

vi) The research will be conducted in compliance with the GUIDELINES FOR GOOD CLINICAL PRACTICE IN HUMAN PARTICIPANTS IN SOUTH AFRICA (2016).

vii) The Company must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from the Committee as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.

viii) A copy of the research report will be provided to the Committee once it is finally approved by the relevant primary party or tertiary institution, or once complete or if discontinued for any reason whatsoever prior to the expected completion date.

ix) The Company has the right to implement any recommendations from the research.

x) The Company reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects/ Company or should the researcher not comply with the conditions of approval.

xi) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER OR COMPLETION OR DISCONTINUATION OF THE TRIAL, WHICHEVER IS THE FIRST.

We wish you success in your research.

Yours faithfully

3/4/2019

Prof Dion du Plessis
Full member: Research Operations Committee & Medical Practitioner evaluating research applications as per Management and Governance Policy

Shannon Nell
Chairperson: Research Operations Committee
Date: 20/4/2019

This letter has been anonymised to ensure confidentiality in the research report. The original letter is available with author of research

RESEARCH OPERATIONS COMMITTEE FINAL APPROVAL OF RESEARCH

Approval number: UNIV-2019-0055

Ms Moniqué van der Westhuizen

E mail: u13113462@tuks.co.za

Dear Ms Van der Westhuizen

RE: CARDIORESPIRATORY EFFECT OF VEHICLE VIBRATION ON HEALTHY TERM INFANTS

The above-mentioned research was reviewed by the Research Operations Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at Private Hospitals, has been approved, subject to the following:

i) Research may now commence with this FINAL APPROVAL from the Committee.

ii) All information regarding the Company will be treated as legally privileged and confidential.

iii) The Company's name will not be mentioned without written consent from the Committee.

iv) All legal requirements with regards to participants' rights and confidentiality will be complied with.

v) All data extracted may only be used in an anonymised, aggregated format and for the purposes of this specific study as specified in the proposal. The data may under no circumstances be used for any other purpose whatsoever.

vi) The Company must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from the Committee as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.

vii) A copy of the research report will be provided to the Committee once it is finally approved by the relevant primary party or tertiary institution, or once complete or if discontinued for any reason whatsoever prior to the expected completion date..

viii) The Company has the right to implement any recommendations from the research.

ix) The Company reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects/ Company or should the researcher not comply with the conditions of approval.

x) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER OR COMPLETION OR DISCONTINUATION OF THE STUDY, WHICHEVER IS THE FIRST.

We wish you success in your research.

Yours faithfully

16/10/2019

Prof Dion du Plessis
Full member: Research Operations Committee & Medical Practitioner evaluating research applications as per Management and Governance Policy

Shannon Nell
Chairperson: Research Operations Committee
Date: 29/10/2019

This letter has been anonymised to ensure confidentiality in the research report. The original letter is available with author of research

Appendix B: Study Risk Analysis

Table 17: Study risk analysis

	Infant car seat					
	Risk	Severity	Likelihood	Total	Mitigation	Notes
1	**Administrative**					
1.1	Not finishing Masters in allocated time	10	5	50	Apply proper time management and have regular meeting to ensure I am still on track and to sort out issues quickly	
1.2	Insufficient funding to perform studies (to buy equipment, car seat, perhaps rent a car, fuel for vehicle)	7	3	21	Be creative in ways equipment can be obtained, manufacture what is needed and borrow if possible	
2	**Participants**					
2.1	**Lack of participants**					Ensure a proper recruitment system is in place and recruit more participants than what is needed
2.1.1	Not getting a hospital to partner with	10	3	30	Try to build the study with organisations with whom we already have a relationship (UP related hospitals, organisations where we have personnel links)	When will it be best to approach the parents? Do they come for regular antenatal visits?

2.1.2	Not receiving ethical clearance	10	5	50	Apply early enough to be able to make 2 rounds of ethical clearance applications in 2018	
2.2	**Participant recruitment**					Recruit participants from multiple sources within constraints
2.2.1	Recruiting enough participants so the study is statistically powerful	8	6	48		
2.2.2	Not finding a gynaecologist or midwife to partner with for recruitment and participant recruitment	9	5	45		
2.3	**Loss of recruited participants**					
2.3.1	Not being informed when infants are born and when they are discharged from hospital	10	5	50	Find a hospital willing to partake in the study and have a plan in place of what must be done when a participating infant is born (information that must be collected, who must be informed, will someone be present for baseline tests, will a caregiver be available during testing to monitor infant)	
2.3.2	If participants are discharged over the weekend	7	4	28	Ask all researchers involved if they are willing to work over a weekend	
2.3.3	Baby becomes irritable during testing	5	6	30	Ensure baby is fed, burped and sleeping within time of testing	

2.3.4	Participants being sick during scheduled testing time	10	4	40	Ensure low-risk pregnancies are recruited	
2.3.6	Participants harmed during study	10	3	30	Ensure all necessary measures are in place to protect participants, with medical equipment available if something does happen	
3	**Methods and Materials**					
3.1	**Experimental setup**					
3.1.1	Mounting of accelerometers	8	4	32	Think carefully about how to mount accelerometers, be creative!	
3.2	**Equipment**					
3.2.1	Availability of suitable vehicle	8	5	40	Use a vehicle from VDG (Quantum), borrow or rent a vehicle [Large vehicle will be required - Inform all staff and student with interest in Quantam of schedule. Prioritise this study over their studies]	For Infant car seat: Relying on the Quantum to be available and then it is required for other tests
3.2.2	Availability of equipment that is required	9	5	45	Borrow/rent physiological measuring equipment from medical reps, manufacture own equipment	
3.2.3	Syncing of different measurement equipment [Vibration and physiology]	10	4	40		
3.3	**Test track**					
3.3.1	Weather conditions	6	5	30		

3.3.2	Hospital having suitable roads and obstacles for defining standard road	8	3	24		
4	**Support Personnel**					
4.1	Not having enough assistance to perform study	9	6	54	Ensure the persons needed for the study is identified beforehand, informed when their help is needed and that enough people are asked to assist with possible back-ups (driver)	
4.2	Not having the necessary support from medical personnel during the study	9	5	45	Find hospital with personnel that are interested in the study and might use some of the data for their own studies as incentive	
5	**Procedure**					
5.1	Time required to perform each study	7	8	56	Ensure equipment is ready to go, requiring minimal 'tuning' when babies are monitored, exclude participants that live too far -> Ensure experimental protocol is set up well and simple to follow	
5.2	Unforeseen problems during testing (equipment malfunction)	9	5	45	Perform preliminary tests before actual testing, perform regular calibration tests, inspect functioning of equipment before every test, take car to preserve the integrity of the equipment	
5.3	Different drivers	5	9	45		

5.4	Variation in testing resulting in different results (vehicle speed, noise levels)	5	9	45	Ensure enough samples are obtained to account for variability, and control environmental conditions as well as possible, measure (vehicle speed, position and interior noise)!	
5.5	Identifying the correct parameters to measure	8	3	24	Perform thorough literature study, consult with people within the field	
5.6	Parents interfering during testing	5	7	35	Inform parents of testing procedure via video and that they cannot interfere during testing, also recruit people in their 2nd pregnancy to have them more relaxed	
5.7	Having access to facilities for baseline tests	7	5	35	Find hospital to partner with who is interested in the study and willing to provide the necessary support	

Appendix C: Recruitment Video Consent

Consent from the Participating Employee to Appear in Video

Policy Reference COM01	Page 1
Forms Communication Policies	COM.F04 Letter of Consent - Media Interview
Issue date February 2015	Version 2

COM.F04 LETTER OF CONSENT BY STAFF MEMBERS OR DOCTORS FOR NETCARE TO ALLOW TRIALOGUE TO INTERVIEW THEM AND TAKE VIDEO FOOTAGE OF THEM WHILST IN A NETCARE FACILITY

I, the undersigned, Raynique Bernardus 9705180600087

(Full name) (Identity number)

hereby give consent to **Netcare Limited**, registration number 1996/008242/06, its subsidiary operations, employees, representatives and agents ("**Netcare**") to allow

University of Pretoria

(Name of media)

- ☐ to interview me and publish information disclosed by me during the interview
- ☒ to take video images of me for use by them in their publication, radio, social media site or TV channel

I understand and agree that I have no claim on any intellectual property rights including but not limited to copyright and ownership of the video footage, and that I will not receive any payment for the photos or video footage.

I am aware that there is the possibility of other media taking the above material and using it in their publications, radio stations or TV channels. The same applies to social media sites, where the material published by the specific media company could possibly be featured on their platforms.

SIGNED AT Netcare Ferncrest ON THIS THE 3 DAY OF 12 20 18

Name of adult: Raynique Signature: [signature]

Permission from the Participating to Film on Site

[redacted]

[redacted]

30 November 2018
Faculty of Health Sciences Research and Ethics Committee

To whom it may concern

Re: Video filming at [redacted]

I hereby wish to confirm that [redacted] Hospital has given permission for a video to be filmed and produced for use for their application to the Ethics Committee as well as for patient information purposes during their research study should it be approved.

All the necessary consent documents as per the [redacted] requirements for filming will be completed on site on the 3rd of December 2018 and the original copies handed to [redacted] management for record purposes.

Yours sincerely

[redacted]
Hospital General Manager
[redacted] Hospital

Appendix D: Informed Consent

Informed Consent to Take Part in Opinion Poll

Having a baby is an amazing experience but one that may be associated with anxiety and stress, especially for first time moms and dads. It is natural that parents worry about all the new things their babies will be exposed to, now that they are no longer protected in the womb.

One of the first new experiences that your baby will experience is driving in a car seated in his/her car seat. Little is known about the health aspects of babies in their car seats traveling in a car. We, as part of the Vehicle Dynamics Group of the University of Pretoria, would therefore like to get a better understanding of our babies' health during driving.

We would appreciate your time in giving us your opinion about this planned study.

TITLE OF STUDY: CARDIORESPIRATORY EFFECT OF VEHICLE VIBRATION ON HEALTHY TERM INFANTS

1) Study background

The American Academy of Pediatrics recommends that all preterm infants undergo monitoring in a car seat before discharge. Many hospitals in Britain and America follow this advice.

We are doing this study to determine if there is an impact on the health of a healthy, term baby who is seated in a car seat that is exposed to the motion associated with normal vehicle travel. The results from this study will extend on the limited body of knowledge regarding babies in car seats during driving. It could lead to future improvements in car seat design and/or best practices for transporting babies in car seats.

2) Why are we doing this opinion poll?

We are conducting an opinion poll to determine whether parents will be interested in participating in our study. We would also like to get some feedback on whether there are any aspects of the study that would make parents hesitant to have their babies participate.

3) What will the opinion poll entail?

You, as informant, will be required to watch a YouTube video that will provide you with more information regarding the study. After watching the information video, you will be required to read the "Informed consent" letter that will be supplied to the parents of the babies. You will then be asked a few questions about the study. This opinion poll should not take more than 15 minutes of your time.

4) Data gathered during the opinion poll

We will gather the following information during the opinion poll:

- Based upon the information provided, would you participate in the study? (Yes/No)
- If there are any specific reasons why you would not participate in the study
- If there are any changes to the study that would make you reconsider participating in the study

5) What are your rights as an informant?
You may withdraw from this opinion poll at any time.

6) Will the study have ethical approval?
The study will have written approval from the necessary Research Ethics Committees of the University of Pretoria before it starts.

7) Financial arrangements
Your participation is voluntary. No compensation will be supplied for your participation in this opinion poll.

8) Confidentiality
All information that we obtain will be kept strictly confidential. All surveys completed will be done so anonymously. We will not have access to any of your personal information, such as your email address or phone number.

9) Opinion poll
Please visit the following link to get access to the opinion poll (as a Google Form):

https://goo.gl/forms/OJ2CLCXTd8fjbHzJ2

CONTACT PERSON

If you have any questions or comments about the study and/or opinion poll, please do not hesitate to contact the researchers.

	Telephone number		Email address
Dr Cor-Jacques Kat	Daytime	012 420 3205 / 072 314 7774	cor-jacques.kat@up.ac.za
	After hours	072 314 7774	
Ms Moniqué van der Westhuizen	Daytime and After hours	073 549 6345	u13113462@tuks.co.za

Consent to participate in this opinion poll

I confirm that I have received, read and understood nature and processes of the opinion poll in this informed consent letter. I am aware that the results of the opinion poll, including personal details, will be anonymously processed into research reports. I am willingly participating in this opinion poll. I understand that there is no penalty should I wish to discontinue with the opinion poll.

Informant's name ………..(Please print)

Informant's signature: ....…………………… Date............................

Witness's Name ....……………..................(Please print)

Witness's signature: ....……………………...
Date.…........................

Informed Consent to Take Part in Study

Dear Parent,

Congratulations on your pregnancy! Thank you for taking the time to consider partaking in this study. As with most experiences with your baby, the first ride home is special. We do not want you as parents to miss out on any part of this special experience by deciding to partake in this study. We have therefore taken great care to make sure that the study will enhance your experience. Your experience and the well-being of your baby is of utmost importance to us.

This informed consent letter will provide you with information regarding the study in order for you to make an informed decision on whether you and your baby will participate in it. If you have any question not covered in this letter please do not hesitate to contact the researchers, Dr Cor-Jacques Kat or Ms Moniqué van der Westhuizen, for clarification.

TITLE OF STUDY: Cardiorespiratory effect of vehicle vibration on healthy term infants

1) Why are we doing this study?

Having a baby is an amazing experience but one that may be associated with anxiety and stress, especially for first time moms and dads. It is natural that parents worry about all the new things their babies will be exposed to, now that they are no longer protected in the womb. One of the first new experiences that your baby will experience is driving in a vehicle seated in his/her car seat.

The American Academy of Pediatrics (AAP) recommends that all preterm infants undergo monitoring in a car seat before discharge. Many hospitals in Britain and America follow this advice.

During this study, we will monitor your baby using simple, stick-on (non-invasive) sensors during three activities: 1) lying in a cot, 2) sitting in a stationary car seat, and 3) sitting in a car seat within vehicle driving around the hospital. You can then select whether you would like us to continue monitoring your baby all the way home or drive yourselves.

We are doing this study to determine if there is an impact on the health of a healthy, term baby who is seated in a car seat that is exposed to the motion associated with normal vehicle travel. The results from this study will extend on the limited body of knowledge regarding babies in car seats during driving. It could lead to future improvements in car seat design and/or best practices for transporting babies in car seats.

2) What will be done during the study?

Once your baby is discharged from hospital after birth, we will proceed to midwifery practice's birth unit at the participating hospital. The study consists of three activities:

	What happens during this activity?	How long will this activity take?
Activity 1	Your baby will be monitored while lying on his/her back in a cot in the hospital.	30 minutes
Activity 2	After activity 1, your baby will be placed in a stationary car seat and monitored again while sitting in the seat while still in the hospital.	30 minutes
Activity 3	You and your baby will then accompany the researchers to the vehicle in which you and your baby will be driven around the hospital, returning to the hospital.	15-30 minutes

You as the parent(s) are allowed to accompany your baby at all times during all three activities of this study. Under no circumstances may your baby be unfastened or removed from the car seat while the vehicle is moving.

What happens after Activity 3?
After Activity 3, you may choose either
1) to use your own transport to go home, or
2) the researchers can continue monitoring your baby while driving you and your baby to your home.

What car seat and vehicle will be used?
A standard ISOFIX car seat will be used and the vehicle will be a Toyota Quantum.

Why can't I use my own car seat and vehicle?
The same car seat and vehicle needs to be used for all the babies in this study. The car seat and vehicle will be fitted with sensors that can measure the motion of the car seat and the vehicle.

How will my baby be monitored and what will be measured?
Your baby's heart rate, breathing rate and blood oxygen saturation levels will be monitored using simple, stick-on (non-invasive) sensors during the study. A camera system will also be used to track the posture of your baby throughout the in-vehicle tests.

What happens if my baby shows an effect on his/her health?

During the study, continuous measurements of your baby's heart rate, breathing rate and blood oxygen saturation levels will be used to monitor your baby's health**.** If your baby shows blood oxygen saturation levels, breathing or heart rate that is below safe levels, the following procedure will be followed: Check monitoring equipment, reposition your baby if it appears that their posture is not good and then stimulating him/her. In the unlikely event that this procedure does not normalise your baby's response, you and your baby will be taken to your paediatrician as a precautionary measure.

3) What are the benefits of this study to my baby?

Your baby will be monitored during their first trip in a vehicle and first trip home. The researchers can also advise you on the best travelling practices currently advised by the American Academy of Pediatrics (AAP).

The researchers will not make any diagnosis or claims regarding the health of your baby. The researchers will only be able to comment on the measurements displayed during the tests and will advise you as a parent to discuss any cautionary observed responses with your health practitioner.

4) What are the benefits of this study to other future babies?

The results from this study will extend on the limited body of knowledge regarding babies in car seats during driving. It could lead to future improvements in car seat design and/or best practices for transporting babies in car seats.

5) What are the risks and discomfort involved?

The risks associated with this study is similar to the risks that you may experience if you were to drive your baby in his/her car seat. Some of the associated risks are however reduced by continuously monitoring your baby, driving outside peak traffic times and using an experienced driver. The tests involved with the study will take less than 2 hours of your time.

6) What help do we need from you as parents prior to the study?

We will require you as parent(s) to inform us once your baby has been born, and when it is expected that your baby will be discharged.

7) Data gathered during the study

The following information will be required from you as a parent:

- Name(s) and surname(s)
- Contact person for the study
- Contact details (contact number and email address) of contact person
- Due date
- Use of transport during pregnancy (public or private transport)
- Time spent travelling during pregnancy (average hours per day)
- Is the combined household income > R3500 per month (Yes or No)
- Do you live within a 30km radius from the participating hospital?
- Contact details of your preferred paediatrician

The researchers will also need to gather the following information regarding your child on the day of discharge:

- Gestational age
- Birth weight
- Weight at testing
- 5-minute APGAR score
- Date of birth

8) WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may withdraw from this study at any time. Your withdrawal will not affect your baby's access to other medical care. The researchers retain the right to withdraw your baby from the study if it is considered to be in his/her best interest. If it is detected that you did not give an accurate history or did not follow the guidelines of the study, your baby may be withdrawn from the study at any time.

9) HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received written approval from the following Research Ethics Committees of the University of Pretoria:

	Telephone numbers	Email address
Faculty of Health Sciences	012 356 3084 012 356 3085	fhsethics@up.ac.za
Faculty of Engineering, Built Environment and Information Technology	012 420 3736	ebit-ehics@up.ac.za

The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human subjects. A copy of the Declaration may be obtained from the researchers should you wish to review it.

10) INFORMATION AND CONTACT PERSON

The contact persons for the study are:

	Telephone number		Email address
Dr Cor-Jacques Kat	Daytime	012 420 3205 / 072 314 7774	cor-jacques.kat@up.ac.za
	After hours	072 314 7774	
Ms Moniqué van der Westhuizen	Daytime and After hours	073 549 6345	u13113462@tuks.co.za

If you have any questions about the study, please do not hesitate to contact the researchers.

11) INSURANCE AND FINANCIAL ARRANGEMENTS

Your participation is voluntary. No compensation will be supplied for your participation in this study.

The researchers are not liable for any additional medical therapy required in the event of your baby displaying any responses below the selected threshold that cannot be resolved by following the stipulated procedures. You will remain responsible for these medical costs.

It is highly unlikely that anything will happen during testing. However, in the unlikely event of a road traffic accident and it is shown that the researchers were either negligent or purposefully put you and your baby at risk, you are covered by the University of Pretoria's insurance policy. In the event of a road accident where the researchers were not at fault, you will need to claim any injuries or damage from the Road Accident Fund as the University will not be held liable.

12) CONFIDENTIALITY

All information that we obtain will be kept strictly confidential. Once we have analysed the information no one will be able to link the data/results to you or your baby. This will be accomplished by assigning a participant number to your baby. This participant number will be used to link all data gathered to the correct baby once the data is being processed. Your baby's face will not be displayed in any photographs or representations linked to the results from the study. Research reports and articles in scientific journals will not include any information that may identify you or your baby.

CONSENT TO PARTICIPATE IN THIS STUDY

I confirm that the person asking my consent for my baby to take part in this study has told me about the nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information in this informed consent letter. I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I am willingly allowing my baby to participate. I have had time to ask questions and have no objection to my baby participating in the study. I understand that there is no penalty should I wish to discontinue with the study.

I have received a signed copy of this informed consent agreement.

Parent's name ……...(Please print)

Parent's signature: ....……………… Date............................

Researcher 1 name ....………………………...(Please print)

Researcher 1 signature ....……………… Date.….........................

Researcher 2 name ....………………………...(Please print)

Researcher 2 signature ....……………… Date.….........................

Witness's Name ....………….................(Please print)

Witness's signature ....…………………...
Date.….........................

Appendix E: Safety Considerations

The following aspects may be taken into account to ensure the safety of participants. These aspects serve as some of the mitigations of the risks listed in Vehicle

- A fire extinguisher must be available in the vehicle in case of a fire
- A safety inspection of vehicle must be performed prior to driving, where the functioning of all critical systems will be observed
- The vehicle selected for the study will have a 3-star NCAP rating, meaning that the vehicle provides average to good occupant protection

Road use

- The researchers must strictly adhere to speed limits while driving
- The road tests may also take place during off-peak traffic times, or between 09h00 and 16h00 and after 18h00, to ensure that minimal vehicles are present during testing
- In addition to the above point, the researchers must attempt to select the route to the house of the participant that will be the safest to travel upon and which will be most likely to have the least traffic

Infant

- Infants must be properly secured in the infant car seat according to manufacturer guidelines
- Infants will not be allowed to wear bulky clothes, as this reduces the efficiency of the restraining system. The infant can be covered with a blanket once secured in the seat
- Tests must be performed in sequence as can be seen in Figure 10, where any apnoeas observed will be referred back to the hospital or the paediatrician of the infant
- The infant is to remain secured in the car seat at all times while the vehicle is in transit

Appendix F: Assessment of Resources

Access to the Study Population

The researchers do not have direct contact with the study population under investigation. The researchers are in discussion with the participating hospital as well as midwifery practice for possible recruitment of participants through these organisations. It is aimed that the participants will be identified and recruited through a trained gynaecologist or midwife during the antenatal visits of expecting parents.

Access to equipment required for the study

The following table lists the equipment required to perform the study, as well as whether the student has access to these pieces of equipment at this point in time. The feasibility of study Option A is highly dependent on the availability of a few critical components, such as a suitable vehicle (the Toyota Quantum), a pulse oximeter as well as infant sensors for the pulse oximeter. Planning will be essential in this study, as a few of the equipment pieces listed below are in high demand in the Vehicle Dynamics Group.

Table 18: Assessment of equipment needed for the study

Equipment	Availability	Notes on availability
Toyota Quantum 2007 d4d	Limited availability	Needs to be coordinated with requirements of VDG staff
ISOFIX car seat	Not available	Still need to buy/borrow a suitable car seat
VBOX	Limited availability	High demand item, use will need to be coordinated with the needs of other VDG staff. Might need to investigate alternative options
MicroAutoBox	Limited availability	High demand item, use will need to be coordinated with the needs of other VDG staff. Might need to investigate alternative options
Triaxial accelerometers	Available	Sufficient number in stock
Sound level meter	Available	Three of these items are available for use
Thermostat	Not available	Should not pose a problem
Seat pad accelerometer	Available	Should not pose a problem
Primary pulse oximeter with recording capabilities	Not available	Investigating purchasing a system as no suitable system could be found within the University of Pretoria to date
Infant sensors for pulse oximeter	Not available	Investigating purchasing sensors as no sensors could be found within the University of Pretoria to date
Camera system	Limited availability	Needs to be coordinated with requirements of VDG staff

Time required to conduct and complete the study

Time required to conduct each test

Referring to Table 19, it can be seen that a total of approximately seven hours is required to perform each test. This time includes the preparation performed before testing (performed the morning of the test day), as well as the time required for the researchers to travel to the participating hospital and back from the home of the participant. It is anticipated that the participants will actively be involved in testing for approximately two hours, however this estimate will vary depending on whether the parents of the participant choose to have the researchers monitor them on the way home as well as the time required to travel to the home of the participant.

Table 19: Breakdown of time required for tests including infants as participants

Task category	Task number	Task	Task description	Maximum time required [min]
1.) Preparation	1.1	Vehicle instrumentation	Place VBOX and MicroAutoBox in vehicle, connect all systems and ensure everything is functioning	60
	1.2	Perform vehicle inspection	Check vehicle tyre pressure, functioning of vehicle lights, indicators and brake lights, fuel level, oil level, water level and any leaks	15
	1.3	Check that all necessary equipment is loaded in vehicle	Use checklist to ensure all necessary equipment has been loaded in the vehicle	5
	1.4	Drive to hospital	Drive from University of Pretoria to the participating hospital	15
	1.5	Prepare equipment for baseline measurements	Remove car seat and pulse oximeter from vehicle and setup in hospital for baseline measurements	20
Total time required for preparation [min]				115
2.) Baseline tests	2.1	Connect pulse oximeter & sensors	Connect the necessary sensors and equipment to the infant, check that measurements can be obtained	10
	2.2	Baseline tests in cot	Perform baseline tests with infant in the supine position, measure heart rate, respiratory rate and oxygen saturation levels	30
Total time required for baseline tests [min]				40
3.) Test 1: Static car seat test	3.1	Place infant in car seat	Place infant in the car seat, fasten infant according to requirements	10
	3.2	Tests in car seat	Perform tests with infant in the car seat, measure heart rate, respiratory rate and oxygen saturation levels	30
Total time required for test 1 [min]				40
4.) Test 2: In-vehicle measurements	4.1	Move infant to the vehicle environment	Move infant from hospital to vehicle, connect all necessary equipment and ensure physiological measurements are being measured correctly	20
	4.2	Drive along mission profile	Drive along the mission profile identified around the hospital	30
Total time required for test 2 [min]				50
5.) Optional addition to Test 2	5.1	Drive to infant's home	Drive along individual roads to each participant's home	45
	5.2	Unload infant and belongings	Help to unload infant and their belongings	15
	5.3	Drive back	Drive back to University or hospital for the next test	45
Total time required for optional addition to test 2 [min]				105
Total maximum time required per test [min]				330

Table 20: Schedule of day of testing 3 infants

Time	Task number	Task
7:00 AM	1.5	Arrive at hospital, prepare equipment for baseline measurements
7:20 AM	2.1	Connect pulse oximeter equipment to infant 1
7:30 AM	2.2	Baseline tests in cot
8:00 AM	3.1	Place infant 1 in car seat
8:10 AM	3.2	Test 1: Car seat
8:40 AM	4.1	Move infant 1 to vehicle
9:00 AM	4.2	Test 2: Drive along mission profile
9:30 AM	4.3	Test 2: Drive to infant 1's home
10:15 AM	4.4	Unload infant 1 and belongings
10:30 AM	4.5	Drive back to hospital
11:15AM	1.5	Arrive at hospital, prepare equipment for baseline measurements
11:35 AM	2.1	Connect pulse oximeter equipment to infant 2
11:45 PM	2.2	Baseline tests in cot
12:15 PM	3.1	Place infant 2 in car seat
12:25PM	3.2	Test 1: Car seat
12:55 PM	4.1	Move infant 2 to vehicle
1:15 PM	4.2	Test 2: Drive along mission profile
1:45 PM	4.3	Test 2: Drive to infant 2's home
2:30 PM	4.4	Unload infant 2 and belongings
2:45 PM	4.5	Drive back to hospital
3:30 PM	1.5	Arrive at hospital, prepare equipment for baseline measurements
3:50 PM	-	Evaluate results gathered from day so far
4:20 PM	2.1	Connect pulse oximeter equipment to infant 3
4:30 PM	2.2	Baseline tests in cot
5:00 PM	3.1	Place infant 3 in car seat
5:10 PM	3.2	Test 1: Car seat
5:40 PM	4.1	Move infant 3 to vehicle
6:00 PM	4.2	Test 2: Drive along mission profile
6:30 PM	4.3	Test 2: Drive to infant 3's home
7:15 PM	4.4	Unload infant 3 and belongings
7:30 PM	4.5	Drive back to university

Time required to complete the study

The study will be completed during 2019, which is the year that the student will be registered for her MEng degree. It is anticipated that the testing phase of the study will take place between February 2019 and May 2019.

Participating members

Medical

The study will require medically trained staff to identify possible participants for the study. The medically trained staff can include gynaecologists or midwives associated with the participating hospital or midwifery practice.

Engineering

Qualified engineers will be responsible for the instrumentation of the test vehicle and car seat. An engineer, with test driving experience and in possession of a valid South African driver's licence will be the driver of the vehicle.

Physiology

A qualified person (either from the Physiology department or from the Neonatology or Paediatrics department of the University of Pretoria) will be recruited to assist in the post-processing and/or interpretation of the cardiorespiratory measurements obtained during testing.

Statistics

A qualified member from the department of Statistics of the University of Pretoria will assist in the statistical analyses of the data obtained during testing. Assistance will also be provided in the experimental design phase of the study.

Adequate facilities to conduct the study

The researchers are in discussion with midwifery practice to make use of their birthing house at the participating hospital to perform the baseline measurements.