USAARL-TECH-SR--2022-12

Test Methodology for Simulation of Human Physiological Measures for Testing of Medical Items in High Vibration Environments

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REPORT DOCUMENTATION PAGE

Form Approved
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1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
18-11-2021	Special Report	Jun 2020 - Sep 2021

4. TITLE AND SUBTITLE

Test Methodology for Simulation of Human Physiological Measures for Testing of Medical Items in High Vibration Environments

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Kinsler, R.[1], Lloyd, A.[1,2], Kroening, L.[1,2], & Caruso, K.[1,2]

5d. PROJECT NUMBER

CO200001

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

U.S. Army Aeromedical Research Laboratory
P.O. Box 620577
Fort Rucker, AL 36362

8. PERFORMING ORGANIZATION REPORT NUMBER

USAARL-TECH-SR--2022-12

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Military Operational Medicine Research Program
504 Scott Street
Fort Detrick, MD 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

USAMRDC

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

DISTRIBUTION STATEMENT A. Approved for public release; distribution unlimited.

13. SUPPLEMENTARY NOTES

[1]U.S. Army Aeromedical Research Laboratory; [2]Goldbelt Frontier, LLC

14. ABSTRACT

The U.S. Army Medical Materiel Development Activity (USAMMDA) Medical Evacuation Program Management Office (MEDEVAC PMO) and the Combat Casualty Care Research Program (CCCRP) of the U.S. Army Medical Research and Development Command (USAMRDC) have requested that the U.S. Army Aeromedical Research Laboratory (USAARL) develop a test methodology for evaluation of medical items in a high vibration environment without the use of human subjects. Testing of medical devices used for patient care during medical evacuation often requires the use of human subjects as live "signal sources" because current simulation technology is susceptible to the same disruptive environmental factors that can interfere with testing of medical devices. A survey of the literature revealed various environmental factors that, when coupled with interaction with the human body, can cause device malfunctions or failures. The most prominent of these factors is the high vibration generated by medical evacuation vehicle rides. Simulation of this type of motion artifact generating test methodology in a laboratory environment will limit the need for human volunteers in future testing, allowing quicker response to test and evaluation requests. This report contains a description of a test methodology for simulation and testing of medical devices in high vibration environments.

15. SUBJECT TERMS

physiological measures, vital signs, medical evacuation, en route care, equipment testing, high vibration

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Loraine St. Onge, PhD
UNCLAS	UNCLAS	UNCLAS	SAR	41	19b. TELEPHONE NUMBER *(Include area code)* 334-255-6906

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Summary

The U.S. Army Medical Materiel Development Activity (USAMMDA) Medical Evacuation Program Management Office (MEDEVAC PMO) and the Combat Casualty Care Research Program (CCCRP) of the U.S. Army Medical Research and Development Command (USAMRDC) have requested that the U.S. Army Aeromedical Research Laboratory (USAARL) develop a test methodology for evaluation of medical items in a high vibration environment without the use of human subjects. Testing of medical devices used for patient care during medical evacuation often requires the use of human subjects as live "signal sources" because current simulation technology is susceptible to the same disruptive environmental factors that can interfere with testing of medical devices. A survey of the literature revealed various environmental factors that, when coupled with interaction with the human body, can cause device malfunctions or failures. The most prominent of these factors is the high vibration generated by medical evacuation vehicle rides. Simulation of this type of motion artifact-generating test methodology in a laboratory environment will limit the need for human volunteers in future testing, which will allow quicker response to test and evaluation requests. This report contains a description of a test methodology for simulation and testing of medical devices in high vibration environments.

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Background

The U.S. military populates the medical equipment sets used on their transport platforms with medical devices identified via the acquisition process, with a heavy emphasis on selecting existing commercial off the shelf (COTS) items. This process has the advantage of reducing the time and costs associated with device development, but the military often initially selects items that are designed for a controlled, hospital environment. In order to safely use carry-on medical devices on board military medical evacuation platforms, candidate devices must undergo a series of laboratory-based tests and validation rides during simulated operational use on the platform. The laboratory tests focus on the environmental factors that may cause serious damage or interfere with the function of the device in the austere medical evacuation environment.

USAARL tests devices intended for use on military medical evacuation helicopters in accordance with (IAW) the Joint En route Care Equipment Test Standard (JECETS), authored by the laboratory in collaboration with the U.S. Air Force Aeromedical Test Laboratory. JECETS has been subsequently agreed upon with test agencies from other services. It contains tailored methods pulled from more generalized environmental test standards and aircraft standards such as Military Standard (MIL-STD) 810G, MIL-STD-461G, and Army Regulation 70-62.

The purpose of the standardized tests are two-fold: 1) to ensure aircraft safety and 2) to ensure safe patient care. The suite of tests that address aircraft safety include Electromagnetic Interference (EMI)/Electromagnetic Compatibility (EMC), Crash Hazard Acceleration, and Explosive Atmosphere. The tests performed to ensure safe device functionality include the Baseline Performance Assessment, Vibration, EMI/EMC, Climatic Tests, Low Pressure (Altitude), Blowing Sand, Blowing Dust, and Blowing Rain. Testing may be further tailored based on the manufacturer's specifications for the device and the intended application during medical evacuation activities. One of the final tests conducted, rotary-wing Flight Testing, assesses the device in a realistic operational environment. These devices are sometimes attached to a human volunteer to improve the realism of the flight scenario. It is not uncommon during Flight Testing that devices will exhibit malfunctions or failures that were not identified during laboratory testing. Because these issues are identified late in the testing timeline, and can sometimes be serious enough to remove a device from consideration for acquisition, significant cost may have been avoided if the errors could be provoked during the laboratory testing phase.

The results from testing provide the foundational information for two documents. One of those documents is the Airworthiness Release (AWR), which allows aircraft-specific use of the tested item in flight. The focus of the AWR is the safety of the aircraft when the item is in use on board, and specifies any restrictions for its use during flight. The other document is the Aeromedical Certification Memorandum (ACM). The ACM addresses patient safety when the medical device is used in the flight environment. This document contains warnings, cautions, and notes specific to the use of the device during medical evacuation. The warnings, cautions, and notes are comprised of information gained by the results of the tests conducted as well as a Medical Risk Assessment conducted with subject matter experts including experienced Flight Surgeons and Aviation Safety Officers.

Considering the potential cost-savings that may occur if unsuitable devices are identified early in the testing process, the USAMMDA MEDEVAC PMO and the CCCRP of the USAMRDC have requested that USAARL develop an improved test methodology for evaluation of medical items without requiring the use of human volunteers.

Methods

A literature search identifying the effects of the medical evacuation environment on measurement of physiological vital signs was conducted. The following key words were used, in various combinations, in a search of the Scopus and PubMed databases: heart rate (HR), respiration rate (RR), electrocardiogram (ECG), defibrillation, oxygen saturation (SpO_2), end-tidal carbon dioxide ($EtCO_2$), ventilation, non-invasive blood pressure (NIBP), vibration, barometric changes, medical equipment failure, medical equipment malfunction, medical evacuation, motion artifact, vibration artifact, vital signs monitor artifact, vital sign signal artifact, diagnostic error, and patient-device interface. The search produced over 500 initial results. This initial list was narrowed down to 86 results after removing citations that did not directly address measurement of vital signs or medical equipment failures during pre-hospital transport, with the exception of a few references summarizing patient transport in general. A third selection was performed to include a few representative articles relevant to each vital sign commonly used during medical evacuation. Each of these remaining articles were reviewed and critical points pertinent to the search topics were summarized. Appendix B contains an annotated bibliography of reviewed articles.

Results

The references identified during the literature search fall into several broad categories. These categories include general patient transport challenges, as well as measurement of ECG and defibrillation, SpO_2, RR, $EtCO_2$, ventilation, and blood pressure (BP). The measurement of each of these vital signs can be impacted, to varying degrees, by factors in the transport environment.

Several of the references in the general category cover a broader topic of patient transport in the medical evacuation environment, with particular emphasis on aeromedical evacuation. This mode of transport presents several unique environmental stressors that are not present during ground transport. Fouts and Mortimer (2018) performed a comprehensive review on the state of the literature relevant to the stresses of flight during aeromedical transport, to include hypoxia, gravitational forces, barometric pressure changes, thermal changes, vibration, humidity, noise, and fatigue. Intas and Stergiannis (2013) identified similar stressors of air transport, along with requirements for selection of appropriately trained personnel and effective medical equipment appropriate to the patients' specific medical needs. Vibration, noise, and barometric pressure exhibit large swings during the course of transport events (Kaloutsakis et al., 2013). Some patients may also be more vulnerable to these environmental factors, such as neonates and children (Bailey et al., 2019). The packaging of these patients can also contribute to worsening of environmental factors, such as increases in noise and vibration transmission through immobilization technologies. Flight crews also rate performance of patient care tasks as significantly more difficult in the helicopter environment compared to hospital settings (Myers et al., 1995). One of the specific difficulties mentioned is measurement of patient vital signs using

medical monitoring equipment. The absence of reliable patient vital signs can impact the type and likelihood of interventions performed by medical care providers (Brown & Prasad, 1997).

While much of the patient transport literature is written about civilian ground and air ambulance transport, the transport of casualties aboard military medical evacuation platforms can represent an even more austere and extreme transport mode. Medical transport operators must balance protection of the crew and platform from hostile threats and terrain with providing a safe and less disruptive ride for the patient. Because of these unique challenges, the U.S. military requires stringent testing for carry-on medical devices. For example, over a 13-year period 34 medical devices were tested by USAARL for suitability according to environmental, electromagnetic emissions, and human factors (Bruckart et al., 1993). Thirty-two percent (%) failed one of the environmental factors, 91% failed to meet electromagnetic interference standards, and 15% of the devices were judged outright unsuitable for use in the medical evacuation helicopter.

One of the key physiological measures captured by patient monitoring devices is the ECG. An ECG records the electrical activity of the heart in graphical form on a monitor, gives insight into HR, and can show distinctive markers of pathology that require immediate intervention. An ECG measurement is also a critical enabler of the use of an automated external defibrillator (AED). An ECG is measured with electrodes placed at standard points on the body. Motion artifact can disrupt the ECG signal due to changes in the impedance of the electrode leads, loss of contact with the electrode head and skin, and the frequency of chest movement during respiration (Kebe et al., 2020). Medical device designers and manufacturers have had success in using algorithms to reduce this type of noise in the ECG signal (Gowri & Rajesh, 2016). ECG measurement has become reliable enough that AEDs have been evaluated for use during rotary-wing transport (Dedrick et al., 1989; Je et al., 2011). Despite the presence of some residual artifacts related to motion, AEDs were shown to perform reliably in the air transport environment and are approved for use on board military medical evacuation aircraft.

SpO_2 is another common vital sign used during patient transport. Monitors perform a type of spectrophotometry called photoplethysmography (PPG) using an infrared light source and photodetector to measure volumetric variations in circulating blood (Castaneda et al., 2018). This information is displayed as a percentage representing the oxyhemoglobin saturation, defined as the ratio of oxyhemoglobin to reduced hemoglobin in arterial blood. HR can also be estimated from the measurement methodology. The most common device used to monitor SpO_2 of patients during transport is a pulse oximeter, with a sensor that lightly clamps onto a fingertip. Pulse oximeters are generally reliable in hospital settings but have shown sensitivity to environmental factors present during transport such as bright light (sunlight), vibration, acceleration, patient movement/posture, and temperature (Wagner & Ruskin, 2007; DeJarnette et al., 1993; Kebe et al., 2020). Mitigation of these factors have taken the form of alternate measurement sites, rubber boots around the fingertip sensors to block ambient light, and complex processing algorithms designed to detect signal loss and motion artifact (Chong et al., 2014; Hravnak et al., 2016). Some devices also incorporate other sensors such as accelerometers to increase the fidelity of the motion detection. From a technological standpoint, pulse oximetry is considered reliable in the transport environment, though temperature and barometric pressure can lead to fluctuations in peripheral perfusion of the patient unrelated to injury or disease progression.

RR is a critical physiological measure that can give immediate indication of a serious change in patient status during prehospital transport. Current technologies measure or derive RR by extraction from other measured vital signs, tracking movement of the thoracic/abdominal area, or measuring respiratory airflow changes that cause rhythmic fluctuations in temperature, humidity, density of carbon dioxide, and sound (Lui et al., 2019). RR extracted from other vital sign measurements, such as ECG, PPG, ballistocardiogram, seismocardiogram, oscillometric cuff pressure pulses, and Korotkoff sounds depends on the quality of those measures and the algorithms used to derive the RR (Hravnak et al., 2016). Sensors such as accelerometers, gyroscopes, radars, and imaging devices are used for volume detection. Ultra wide band radar has received much attention as an RR method due to simplicity and non-contact form factors, but this method is affected by patient and environmental movement (Eren et al., 2019). Most other mechanical measurement methods are affected by motion artifact as well, but chemical and humidity sensors exhibit insensitivity to this environmental factor. Chemical sensors enable method called capnography to measure $EtCO_2$ levels (Kebe et al., 2020) allowing derivation of RR. Accurate measurements of RR and $EtCO_2$ are particularly important when evaluating the efficacy of patient interventions using non-invasive breathing assistance (such as a bag valve mask) or invasive methods such as mechanical ventilators (McLachlan et al., 2019). Mechanical ventilators can be affected by changes in ambient atmospheric pressure, as are present in the hypobaric condition of aeromedical transport (Boussen et al., 2014). Accurate sensing of patient respiratory metrics is key to prevention of hypoxia and hyperventilation when using ventilation interventions.

Measurement of BP during patient transport can be critical to monitoring the condition of trauma and disease patients. BP measurements can be presented as the ratio of systolic pressure (arterial pressure when the heart beats) over the diastolic pressure (pressure when the heart is between beats), or as the mean arterial pressure. Systolic and diastolic measurement can be collected via auscultation where an arm cuff is inflated until the blood flow is occluded and then slowly released while a care provider listens for Korotkoff sounds, but this method is nearly impossible to accurately perform in the noisy helicopter transport environment (Prasad et al., 1994). Pulse oximeters can be used to estimate the systolic BP in conjunction with an arterial occlusion with a cuff, but this method does not provide the diastolic pressure and is vulnerable to the same factors that affect oxygen saturation measurement (Talke, 1991). Invasive BP measurement has been shown to be more accurate than non-invasive methods (McMahon et al., 2012), but placing the arterial catheter in an appropriate artery and preventing dislodgement during transport conditions is challenging.

The majority of carry-on medical monitors use the principle of oscillometry to measure BP. This method uses an automated cuff to inflate above the systolic BP level, and then slowly deflates to a sub-diastolic level, while measuring the oscillations of external pressure pulses associated with blood volume changes around an artery (Chandrasekhar et al., 2019). This method is particularly vulnerable to movements associated with respiration, heart rate variability, patient voluntary motion, vehicle vibration, and ambient noise due to the use of the pneumatic cuff. Medical providers do not always realize the extent of the disruptions caused by motion because oscillometric BP measures are presented as discrete values, not as a continuous waveform, and unsuccessful measurement attempts are automatically repeated by the device (Van Horn et al., 2001). Medical device manufacturers have incorporated sophisticated algorithms to combat this interference, testing their systems against simulated motion artifacts on

generated waveforms. However, waveform simulators are not capable of taking into account the transfer function between arterial pressure in the limb, air pressure in the cuff, cuff bladder size, placement of the cuff, and the material from which the cuff is made (Gersak et al., 2009). Improvements in medical device and algorithm design to combat motion artifact will likely require more realistic evaluation methods (Alpert et al., 2020).

Discussion

The results of the survey of the literature suggest that high vibration is a factor in the transport environment that can have a significant impact on the function and accuracy of carry on medical equipment. Appendix C contains a summary of the warnings, notes, and cautions from *Aeromedical certification memorandum (ACM) for Patient Movement Items (PMI) aboard Army H-60, UH-72, CH-47, and MH Rotary-wing Aircraft (ACM-2018 Revision 3)* specific to high vibration. The types of devices tested that exhibited issues during high vibration include patient monitors, defibrillators, ventilators, and suction devices. Noted issues range from unexpected shutdowns to inaccurate measurements triggered by high vibration. The literature survey also suggests that measurement of NIBP, especially using the oscillometric method using an automated cuff, was particularly sensitive to motion artifact. A test methodology that accurately recreates the dynamic motion interactions present during medical evacuation transport will allow laboratory-based testing of NIBP measurement devices.

Test Methodology

As described in section 2.3.1 of the JECETS document (2012), vibration testing should be conducted as follows:

> Prior to testing, a performance test will be conducted on the test article IAW the test plan. The test article will typically be secured directly to the vibration table, unless otherwise requested by the test manager. Any deviations in securing will be noted in the test plan. In general, the structural integrity, including any securing hardware, should not be compromised. Aeromedical equipment must perform to its expected functionality during exposure to vibration. This test will be performed using MIL-STD-810G with Change 1, Method 514.7 (2014), as guidance. The test article will be subjected to rotary-wing, jet, turbo-prop, and tiltrotor vibration profiles representing lifetime exposures. Unless contraindicated or with few exceptions, the test article will also be subjected to an operational composite wheeled-vehicle vibration profile. The test article will be tested on three axes: x, y, and z, using specific breakpoints. During lifetime tests, the test article will be expected to function properly during the pre- and post-tests. Any anomalies experienced during a lifetime exposure test will be evaluated for repeatability during in-flight testing.

Notable is the instruction to secure the test article directly to the vibration table, unless otherwise requested by the test manager. Figure 1 shows an example of a typical vibration test setup (Fiebel, 2018) for a patient monitor (obscured since the monitor was a developmental device).

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Figure 1. Vibration test setup for a patient monitor (example).

The main body of the monitor is secured directly to the vibration table. The vital signs simulators are placed on a separate surface, including the BP simulator. The BP cuff, inside the yellow box in the photo, is not placed on the surface of the vibration table because there is no fixture for its attachment. In this example, simulated NIBP signals are provided via the Fluke® ProSim™ 8 Vitals Signs Simulator (Fluke Biomedical, 2016). This simulator uses an onboard pump and a series of valves to create pressure pulses directly in the pneumatic line attached to the port for the BP cuff. The BP cuff itself is wrapped around a non-yielding cylindrical object, called a mandrel. This object is meant to mimic the shape and volume of the human arm. Different sizes are produced to mimic various human arm sizes, from infants to bariatric individuals.

Engineers at USAARL have made previous attempts to create a mandrel type fixture that would permit the incorporation of foam or other materials to create a more realistic tissue-like interface for securing of the BP cuff. An example of this prototype design can be seen in Figure 2. A developmental wireless BP cuff (obscured in the photo) was attached to demonstrate the intended placement.

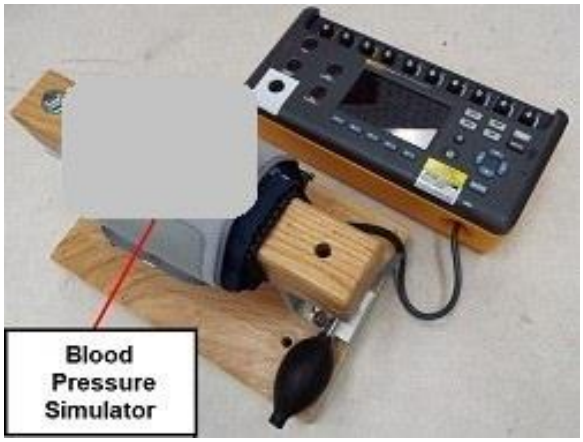

Figure 2. Conceptual patient arm fixture with Fluke® ProSim 8 attached.

The purpose of this fixture is to secure it to the vibration table, along with the body of the test device, to recreate some of the motion artifact inherent during the interaction of the cuff with the human arm during vibration. This design was unsuccessful at replicating this biodynamic interaction. The tested device functioned well during laboratory vibration testing, but exhibited unreliable function during flight testing while attached to a human volunteer.

Members of the Association of the Advancement of Medical Instrumentation (AAMI) Sphygmomanometer Committee have drafted International Organization for Standardization (ISO) 81060-4 (Alpert et al., 2020), a proposed international test standard to evaluate oscillometric BP measurement devices that claim to compensate for motion artifact. The procedures within the standard propose the use of a test device capable of reproducing standard motion profiles from transport vehicles while the monitor is attached around a standardized mandrel fixture. The fixture proposed in the draft standard is plastic pipe of an appropriate diameter, wrapped with foam. The proposed fixture is similar to the prototype device shown in Figure 3, and a similar lack of biofidelity may prove detrimental to the success of the design.

The medical simulation market also contains technologies with greater fidelity to human form factor, but these devices are more commonly used for training of care providers. An example of this type of technology is the Laerdal Medical SimPad® Blood Pressure Trainer, as seen in Figure 3. It is designed to mimic a human arm, with internal lines functioning as blood vessels, and pressure pulses generated by a pump controlled via a tablet.

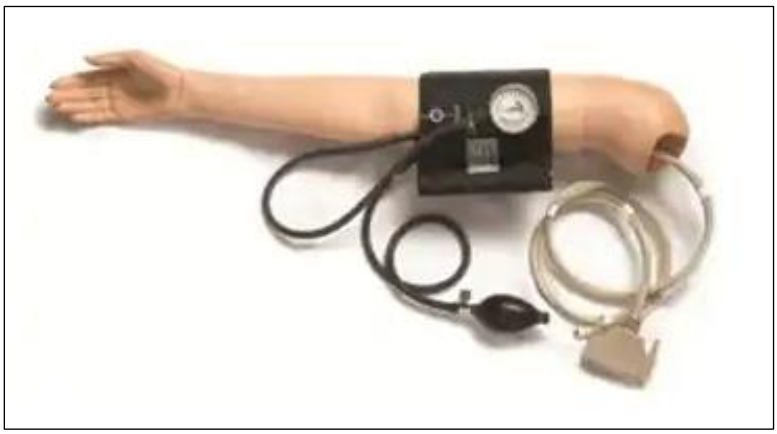

Figure 3. Laerdal Medical SimPad® Blood Pressure Trainer.

This type of device permits measurement of simulated BP using manual auscultation and palpation of pulses. It is not intended for use with automated electronic oscillometric monitors, however. Auscultation is not a method used during helicopter transport due to the noise present in the cabin and the helmets worn by the flight paramedics. The mechanical compliance of the material of the arm is closer to that of human tissue to permit reasonable palpation, but it does not behave dynamically the same way as the human arm during vibration.

Human biodynamic reactions to whole-body vibration have been studied extensively with a focus on occupational exposures. Examples of occupational exposure would include heavy equipment operators or pilots of aircraft spending hours every year exposed to particular vehicle vibrations. Standards such as ISO 2631 parts (1-5) address these exposures, with an emphasis on long-term occupational exposures. Less research has been conducted on acute exposures experienced by patients in the supine posture during aeromedical evacuation. Studies using healthy humans focused on characterization of the biodynamics of the human in a supine posture reveal complex motions associated with the inputs from the vehicle, voluntary human motion, compression of the tissues, and out of phase motion for restrained segments (Kinsler, 2019).

Additionally, weight, anthropometry, gender, and muscle stiffening can affect these biodynamic behaviors (Rahmatalla, 2021).

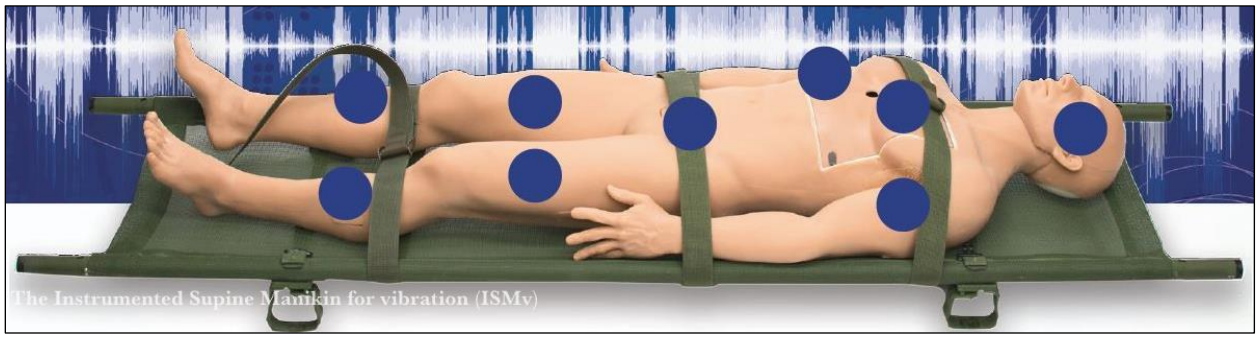

Figure 4. ActiBioMotion, LLC Instrumented Supine Manikin for vibration with sensor locations highlighted.

With these considerations, USAMMDA supported the development of a test manikin as a surrogate for supine human response to repeated shock and vibration (Figure 4).

The intended use of this manikin was to reduce the need for human subjects when doing initial evaluations of en route care technologies such as immobilization systems, litters, and medical interiors of transport vehicles. The third generation of this test tool is an instrumented supine manikin designed to mimic human response to whole body vibration within 90 – 95% fidelity (DeShaw, 2019). The design and validation of this manikin was drawn from multiple studies with healthy humans in the supine posture.

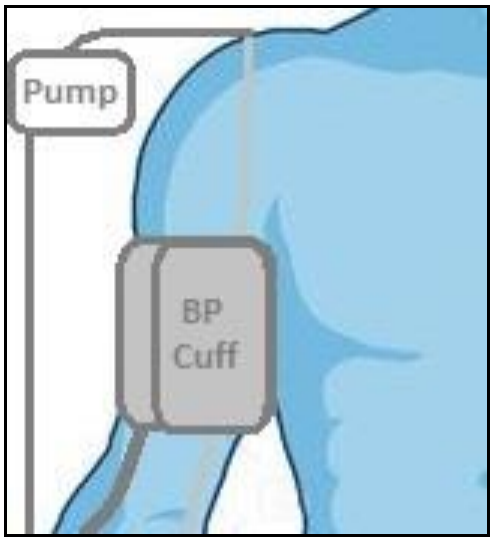

Figure 5. Biofidelic BP test fixture concept.

In order to recreate a realistic dynamic interaction between oscillometric BP cuff and human arm/torso during vibration testing, a BP simulator should incorporate a test fixture/mandrel capable of producing those biodynamic movements. A conceptual design for such a fixture is shown in Figure 5.

This conceptual test fixture would be formed like the arm and torso of the human body, constructed of materials with the same vibration transmissibility properties as those measured on supine humans. Within the arm, lines would run beneath the material surface at an appropriate depth to approximate human blood vessels. Within these lines, air or a type of hydraulic fluid would be pulsed at biological accurate pressures and patterns to approximate human BP. This simulation form would be capable of being affixed directly to the vibration table or secured to a litter in the same manner as a supine patient. Construction of such a test fixture would require a combination of BP simulator technology, medical manikin simulation technology, and human vibration transmissibility replication. It is clear that these separate areas of expertise are already present in the commercial market.

The vibration test methodology for devices with oscillometric BP measurement with a cuff would follow the same basic procedures as defined in JECETS section 2.3.1. The profiles, timed exposures, and setup would be the same with one exception. The biofidelic BP test fixture would be affixed directly to the vibration table, or secured to a litter on the vibration table, and the cuff would be placed around the "arm" of the fixture. Functional checks of the test device during vibration would take place as usual.

Criteria for Evaluation

The constructed test fixture proposed in the previous section would require evaluation and validation before adoption as part of as a standardized test method. This assessment would require two phases: 1) BP simulation and 2) biodynamic fidelity.

The BP simulation phase would involve comparisons between benchmark human subject measurements ("gold standard" invasive BP versus non-invasive BP), established performance of COTS BP simulation devices currently used by the military medical community, and performance of the test fixture. This phase of validation will be conducted in a non-vibration environment. The ISO Standard No. 81060-5:2020 describes the requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers. It will serve as a guide for constructing test methods to verify the static pressure, pulse rate, oscillation amplitudes, and shapes of the text fixture's BP simulation.

The biodynamic fidelity phase would involve testing the form of the fixture for similarities to the human body in terms of realistic limb and torso movement, tissue compliance and resistance during cuff inflation, and stiffness of the "arteries" inside of the limb. USAARL has performed multiple characterizations of human whole body vibration over the course of the last decade, specific to casualty transport on medical evacuation platforms (Kinsler et al., 2018, 2019, 2020; Rahmatalla et al., 2020, 2021). The laboratory has a test platform called the Multi-Axis Ride Simulator (MARS), capable of replicating collected vehicle ride signatures in the range relevant to human whole body vibration with great accuracy.

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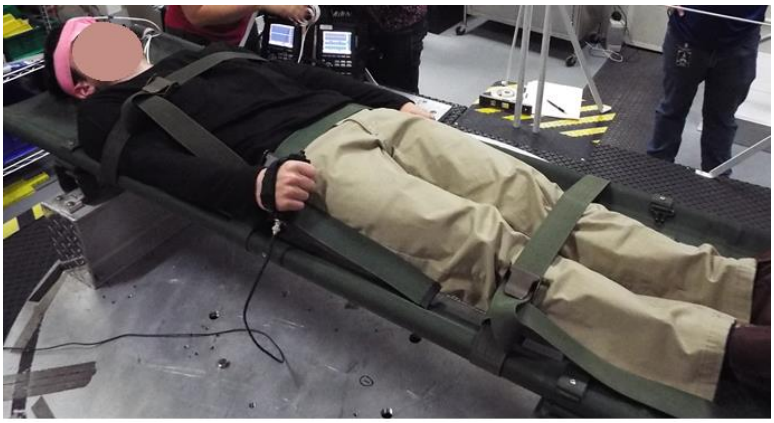

Figure 6. Volunteer on the Multi-Axis Ride Simulator.

Figure 6 shows an example of a human subject on the MARS platform, secured to a medical litter simulating a patient transport scenario. Subjects exposed to this testing method are instrumented with accelerometers, gyroscopes, strain gauges, and other relevant sensors to measure the biodynamics of the body's movement during vehicle vibration. A comparison between characterization testing of human volunteers, with a focus on the arm and torso interaction, and similar testing with the test fixture proposed above during oscillometric BP collection would serve as validation of the biodynamic fidelity of the text fixture.

Conclusion

This study included a survey of the literature describing the common failures of medical devices during evacuation transport, identifying factors that are not currently simulated during laboratory testing. The following information was learned:

- High vibration during medical transport is a common source of medical device malfunctions or failures.
- Oscillometric measurement of NIBP is particularly vulnerable to motion artifact caused by patient movement or vehicle vibration.
- BP simulators on the market do not recreate the dynamic interaction between the patient's arm, BP cuff, and environment that cause many of these failures.
- The expertise identifying the simulation of BP pulses in the human arm, the biodynamic behavior of the human body during whole body vibration, and the simulation of the human form for medical manikins currently exists.
- The union of these areas of expertise would permit the construction of a test fixture that would permit laboratory-based vibration testing for NIBP measurement devices.
- A test methodology using the proposed test fixture, and the draft ISO 81060-4 standard, has been defined.
- Criteria for evaluation and validation of the test fixture was proposed.

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Appendix A. Acronyms and Abbreviations

AAMI	Association of the Advancement of Medical Instrumentation
ACM	Aeromedical Certification Memorandum
AEDs	automated external defibrillator
AWR	Airworthiness release
BP	Blood pressure
CCCRP	Combat Casualty Care Research Program
CO_2	Carbon dioxide
COTS	Commercial off the shelf
ECG	Electrocardiogram
$EtCO_2$	End-tidal carbon dioxide
HR	Heart rate
IAW	In accordance with
JECETS	Joint En route Care Equipment Test Standard
MARS	Multi-axis ride simulator
MEDEVAC	Medical evacuation
NIBP	Non-invasive blood pressure
PMI	Patient movement items
PMO	Program management office
PPG	Photoplethysmography
RR	Respiration rate
SpO_2	Oxygen saturation
USAARL	U.S. Army Aeromedical Research Laboratory
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRDC	U.S. Army Medical Research and Development Command

Appendix B. Annotated Bibliography

Vital Signs - General

Stresses of Flight during Aeromedical Transport: An Integrated Review
Air Force Research Laboratory technical report AFRL-SA-WP-TR-2018-0010
Published in *Defense Technical Information Center*, 2018.
DOI: (not applicable [n/a])

By Fouts, B., & Mortimer, D.

Abstract: The complexity of the aeromedical transport environment presents medical providers with a unique set of challenges. The majority of these challenges are caused by the impact of the stresses of flight on various injury and disease states. The stresses of flight include hypoxia, gravitational forces, barometric pressure changes, thermal changes, vibration, humidity, noise, and fatigue. Unfortunately, there is limited knowledge of the influence of the stresses of flight on patient care during aeromedical transport. This study aimed to investigate the current knowledge base related to the impact of the stresses of flight on injury and disease management during aeromedical transport to identify key areas for future research. A literature search of the PubMed, Cumulative Index to Nursing and Allied Health Literature, Web of Science, and Defense Technical Information Center databases was conducted to identify existing studies published between 2003 and 2014 investigating the impact of the stresses of flight on injury and disease management during aeromedical transport. Whittemore and Knafl's five-step process for integrative reviews was used to identify relevant articles. In total, 7141 unique titles were pulled from the four databases. After reviewing the unique titles for the relevance to injury and disease management during aeromedical transport, 1088 abstracts were reviewed. A total of 928 abstracts did not apply to the area of interest and 160 full text articles were reviewed. Of the 160 full text articles reviewed, 97 articles were considered relevant to this study. The relevant articles suggest the predominance of literature is on hypoxia and barometric pressure. There were few articles on the other stresses of flight. Through the investigation of the stresses of flight and their impact on injury and disease within the aeromedical transport domain, gaps evident in the available research were identified. Understanding the current state of knowledge on the stresses of flight will enable solutions to improve patient care and safety during aeromedical transport.

Critical points:

- Comprehensive literature review of stresses of flight associated with aeromedical transport.
- Inadequate research on the impact of these stresses of flight have on injury and/or disease management: Vibration, humidity/ dehydration, thermal changes, fatigue, G-forces, and noise.
- The majority of the literature focused on hypoxia and barometric pressure changes.

- Future research is needed to characterize and understand the impact of fatigue, noise, vibration, G-forces, humidity/dehydration, and thermal changes on patient outcomes in patients with various types of injuries and diseases.

Risk Factors in Air Transport for Patients
Published in *Health Science Journal*, 2013.
DOI: (n/a)

By Intas, G., & Stergiannis, P.

Abstract: Background: The units that are used for an air transport are: the helicopter which covers distances up to 250 kilometers (km) and the aircraft used for longer distances. By air, the time needed is reduced to half or even to one third compared to terrestrial transportation. Aim: The aim of this review was to investigate the risk factors in air transport for patients via seeking literature. Method and Material: Literature review based on studies and reviews derived from international (Medline, PubMed, Cinahl, Scopus) data bases concerning risk factors in the context of air patient transfer. Results: Important disadvantages of air transports are stress during flight, oxygen partial pressure reduction - hypoxia, reduction of the barometric pressure, temperature reduction, moisture reduction - dehydration, noise, vibrations, acceleration forces (G), and fatigue. The right selection of the staff and the equipment is very important in transports. Attention should be paid before and during transports, and at the arrival at the area of destination. During the transport, a bag with the right equipment should accompany the patient. Anything that it may need to be done during the transport must be done before the start of the transport. Finally, we shouldn't forget that the key for a safe transport is the stabilization of the patient before the transport and the safest transport is the one that never happened. Conclusions: It is very important for healthcare workers who transfer patients by air to be trained on identifying factors that can prove dangerous for the patient.

Critical points:

- Literature review of risk factors involved with aeromedical transport.
- Important disadvantages of air transports are stress during flight, oxygen partial pressure reduction (hypoxia), reduction of the barometric pressure, temperature reduction, moisture reduction (dehydration), noise, vibrations, acceleration forces (G), and fatigue.
- Explains how each factor triggers a human physiological response and details what that response may look like.

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Modern Neonatal Transport: Sound and Vibration Levels and Their Impact on Physiological Stability

Published in *American Journal of Perinatology,* 2019.
DOI: 10.1055/s-0038-1668171

By Bailey, V., Szyld, E., Cagle, K., Kurtz, D., Chaaban, H., Wu, D., & Williams, P.

Abstract: Objective: To measure sound and vibration in rotary wing air transport (RWAT) and ground ambulance transport (GAT), comparing them to current recommendations, and correlating them with physiological stability measures in transported neonates. Study Design: This is a prospective cohort observational study including infants ≤ 7 days of age transported over an 8-month period. Infants with neurologic conditions were excluded. Sound and vibration was continuously measured during transport. Transport Risk Index of Physiologic Stability (TRIPS) scores were calculated from vital signs as a proxy for physiological stability. Results: In total, 118 newborns were enrolled, of whom 109 were analyzed: 67 in RWAT and 42 in GAT. Peak sound levels ranged from 80.4 to 86.4 A-weighted decibels (dBA) in RWAT and from 70.3 to 71.6 dBA in GAT. Whole-body vibration ranged from 1.68 to 5.09 meters per second squared (m/s^2) in RWAT and from 1.82 to 3.96 m/s^2 in GAT. Interval TRIPS scores for each infant were not significantly different despite excessive sound and vibration. Conclusion: Noise levels during neonatal transport exceed published recommendations for both RWAT and GAT and are higher in RWAT. Transported infants are exposed to vibration levels exceeding acceptable adult standards. Despite excessive noise and vibration, levels of physiological stability remained stable after transport in both RWAT and GAT groups.

Critical points:

- Noise levels during the transport of neonates continue to exceed published recommendations in both air and ground transport vehicles.
- Noise levels are significantly higher in rotary wing ambulance transport compared with ground ambulance transport.
- Neonates continue to be exposed to vibration levels that may be harmful based on acceptable adult standards.
- Despite these exposures, neonates remained stable after transport.

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Design and Evaluation of a Multi-sensor Unit for Measuring Physiological Stressors of Medical Transport

Published in *ASME International Mechanical Engineering Congress and Exposition, Proceedings (IMECE)*, 2013.
DOI: 10.1115/IMECE2013-65435

By Kaloutsakis, G., Reimer, A., Jeong, D., & Lee, K.

Abstract: Patients who undergo inter-hospital transfer experience increased relative mortality, ranging from 10 to 100% higher than non-transferred patients. The high-cost, increased risk of complications, and poor outcomes of transferred patients warrant the critical examination of potential causes. One of the major causes may be the external stressors that patients are exposed to during medical transport. To realize simultaneous measurements of external stressors, we developed a multisensor unit for measuring vibration, noise, ambient temperature, and barometric pressure. For preliminary evaluation, the sensor unit was tested on 29 medical transports, 11 air transports by a helicopter and 18 ground missions by an ambulance. The average whole-body vibration for each air and ground transport was calculated at 0.3510 m/s^2 and 0.5871 m/s^2, respectively. Air transports produced much higher levels of noise than the ground transports. We found no significant difference between the two modes in terms of average temperature and the temperature changes. Barometric pressure drops significantly during air transport, indicating potential use of this data for automatic mode classification.

Critical points:

- Development of a multisensory unit to measure vibrations, noise, ambient temperature and barometric pressure.
- The average whole-body vibration for each air and ground transport was calculated at 0.3510m/s^2 and 0.587 m/s^2, respectively.
- Noise increases and barometric pressure drops significantly during air transport.

Influence of the Helicopter Environment on Patient Care Capabilities: Flight Crew Perceptions

Published in *Air Medical Journal*, 1995.
DOI: 10.1016/1067-991X (95)90027-6

By Myers, K. J., Rodenberg, H., & Woodard, D.

Abstract: Introduction: Flight crew perceptions of the effect of the rotary-wing environment on patient-care capabilities have not been subject to statistical analysis. We hypothesized that flight crew members perceived significant difficulties in performing patient-care tasks during air medical transport. Methods: A survey was distributed to a convenience sample of flight crew members from 20 flight programs. Respondents were asked to compare the difficulty of performing patient-care tasks in rotary-wing and standard (emergency department or intensive care unit) settings. Demographic data collected on respondents included years of flight experience, flights per month, crew duty position, and primary aircraft in which the respondent worked. Statistical analysis was

performed as appropriate using Student's T-Test, type III sum of squares, and analysis of variance. Alpha was defined as $p < 0.05$. Results: Fifty-five percent of programs (90 individuals) responded. All tasks were significantly rated more difficult in the rotary-wing environment. Ratings were not significantly correlated with flight experience, duty position, flights per month, or aircraft used. Conclusions: We conclude that the performance of patient-care tasks are perceived by air medical flight crew to be significantly more difficult during rotary-wing air medical transport than in hospital settings.

Critical points:

- Patient care capabilities are perceived by healthcare workers as significantly worse in a helicopter transport setting compared to a hospital setting.

Effect of Vital Signs on Advanced Life Support Interventions for Prehospital Patients
Published in *Prehospital Emergency Care*, 1997.
DOI: 10.1080/10903129708958808

By Brown, L. H., & Prasad, N. H.

Abstract: Objective. Routine vital signs assessment is considered a fundamental component of patient assessment. This study was undertaken to determine whether advanced life support (ALS) emergency medical service (EMS) providers depend on vital signs information in managing their patients. Methods. Emergency medical technician-paramedics (EMT-Ps) and EMT-Intermediates (EMT-Is) were presented with 20 randomized patient scenarios that did not include vital signs information. The participants were asked to identify all of the interventions they would perform for each hypothetical patient. At least six weeks later, the same scenarios were presented in a new order, with vital signs information, and the participants again identified the interventions they would perform. The participants' estimations of the patients' blood pressures, as well as the frequencies with which 18 specific interventions were performed, were compared between the no-vital signs and the vital signs groups using chi-square or Fisher's exact test, with an alpha value of 0.05 considered significant. Results. Fourteen EMT-Ps and 16 EMT-Is completed both the no-vital signs and vital signs portions of the study, for a total of 1160 hypothetical patient encounters. When vital signs were given, the EMT-Is were more likely to apply a cardiac monitor (65.2% versus 80.1%, $p = 0.000$), more likely to start at least one intravenous (IV) line (82.1% versus 87.8%, $p = 0.038$), and more likely to administer a medication (1.3% versus 5.6%, $p = 0.003$). The EMT-Ps were also more likely to apply a cardiac monitor (84.4% versus 90.3%, $p = 0.041$), more likely to run an IV at a "wide open" rate (9.5% versus 19.0%, $p = 0.004$), and less likely to identify patients as being hypotensive (39.9% versus 26.4%, $p = 0.004$). Conclusion. The presence or absence of vital signs information does influence some of the patient care decisions of EMS providers; however, the clinical implications of these decisions are unclear. Further studies are needed to determine whether ALS providers can adequately manage actual patients without obtaining vital signs.

Critical points:

- The presence of vital signs measurements affect the types of interventions medical providers perform in the prehospital environment.

Laboratory and Flight Tests of Medical Equipment for Use in U.S. Army Medevac Helicopters

Published in *Air Medical Journal*, 1993.
DOI: 10.1016/S1067-991X(05)80198-1

By Bruckart, J. E., Licina, J. R., & Quattlebaum, M.

Abstract: When used in an air medical setting, medical equipment designed for use in hospitals can fail from the stresses of in-flight use, or they interfere with critical rotor-wing aircraft systems. From January 1989 to June 1992, 34 medical devices, including monitor/defibrillators, infusion pumps, vital-signs monitors, ventilators, and infant transport incubators, were tested under extreme conditions of temperature, humidity, altitude, and vibration (MIL-STD 810D). Electromagnetic emissions and susceptibility were measured (MIL-STD 461C and 462), and human factors were evaluated. The devices were flight tested in a UH-60 MEDEVAC helicopter. Thirty-two percent of the medical devices failed at least one environmental test, and 91% of the devices failed to meet electromagnetic interference standards. Failures included excess conducted and radiated emissions and susceptibility to radiated emissions. Five (15%) of the devices were judged unsuitable for use in the UH-60 MEDEVAC helicopter. Testing is critical to discover the ability of a medical device to perform in the harsh rotary-wing MEDEVAC environment. Failure of a device or interference with aircraft systems can result in loss of a patient or aircrew.

Critical points:

- Detailed explanation of USAARL airworthiness testing; describes each vital sign with great detail.
- Thirty-four medical devices were tested under a MEDEVAC environment; electromagnetic emission and human factors were evaluated.
- Thirty-two percent failed one of the environmental factors; 91% failed to meet electromagnetic interference standards.

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Electrocardiogram and Defibrillation

Human Vital Signs Detection Methods and Potential Using Radars: A Review
Published in *Sensors*, 2020.
DOI: 10.3390/s20051454

By Kebe, M., Gadhafi, R., Mohammad, B., Sanduleanu, M., Saleh, H., & Al-Qutayri, M.

Abstract: Continuous monitoring of vital signs, such as respiration and heartbeat, plays a crucial role in early detection and even prediction of conditions that may affect the wellbeing of the patient. Sensing vital signs can be categorized into: contact-based techniques and contactless based techniques. Conventional clinical methods of detecting these vital signs require the use of contact sensors, which may not be practical for long duration monitoring and less convenient for repeatable measurements. On the other hand, wireless vital signs detection using radars has the distinct advantage of not requiring the attachment of electrodes to the subject's body and hence not constraining the movement of the person and eliminating the possibility of skin irritation. In addition, it removes the need for wires and limitation of access to patients, especially for children and the elderly. This paper presents a thorough review on the traditional methods of monitoring cardio-pulmonary rates as well as the potential of replacing these systems with radar-based techniques. The paper also highlights the challenges that radar-based vital signs monitoring methods need to overcome to gain acceptance in the healthcare field. A proof-of-concept of a radar-based vital sign detection system is presented together with promising measurement results.

Critical points:

- Dry ECG electrodes have high electrode tissue impedance (ETI) due to poor contact with the skin and are prone to motion artifacts (such as aircraft vibration).
- Standard placement of the electrodes must be followed in order to obtain accurate signals.
- Motion artifact (MA) of the lead electrodes and change in impedance of the electrodes due to respiration causes an amplitude modulation of the ECG data. The inhaling and exhaling process during respiration causes an increase and decrease of the heart rate, respectively, and hence, produce a frequency modulation in the ECG signal for the detection of heartbeat.

Muscle and Baseline Wander Artifact Reduction in ECG Signal Using Efficient RLS Based Adaptive Algorithm
Published in *International Journal of Intelligent Systems & Applications*, 2016.
DOI: 10.5815/ijisa.2016.05.06

By Gowri, T., & Rajesh, K. P.

Abstract: When we acquiring ECG signal from the person, the signal amplitude (PQRST) and timing values are changes due to various artifacts. The different artifacts are baseline wander, power line interference, muscle artifact, and motion artifact as well as channel

noise, which is added during the transmission of the signal for diagnosis purposes. The adaptive filters play vital role for reduction of noise in the desired signals. In this paper we proposed block based error normalized Recursive Least Square (RLS) adaptive and sign based RLS adaptive algorithms, which are used for reduction of muscle artifact noise and baseline wander noise in the ECG signal. From the simulation result we analyzed that comparing to Least Mean Square algorithm, the proposed RLS algorithm, gives fast convergence rate with high signal to noise ratio and less mean square error.

Critical points:

- When acquiring the ECG signal from the patient, signal amplitude and timing values are changed due to various artifacts.
- The different artifacts are baseline wander, power line interference, muscle artifact, motion artifact, and channel noise, which is added during the transmission of the signal for diagnosis purposes.
- The algorithm described in the document was successful at reducing muscle artifact and electrode motion noise in the ECG signal.

Defibrillation Safety in Emergency Helicopter Transport
Published in *Annals of Emergency Medicine*, 1989.
DOI: 10.1016/S0196-0644(89)80318-X

By Dedrick, D. K., Darga, A., Landis, D., & Burney R. E.

Abstract: Rotary aircraft play a growing role in the transport of critically ill patients who may require emergency treatment, including defibrillation, during transport. The close quarters and proximity of vital electronic equipment have generated concern among personnel carrying out defibrillation in the air. We address the chief safety issues in helicopter defibrillation by providing measurements of the transient current leakage resulting from contact with a paddle and tested in-flight electronic interference. A survey of the defibrillation experience of helicopter programs was also collected. Our data show that airborne defibrillation is safe. A maximum of 1.5 milliamps (mA) of transient current leakage was measured from a standard battery-powered defibrillator, well within the accepted safety standard of 50 mA. In flight, there was no interference with the avionics or medical equipment, and adequate clearance was available for personnel. Of the helicopter programs surveyed, 69 (87%) had defibrillated in flight without incident. We conclude that defibrillation can be performed in the helicopter without hesitation, whether on the ground or in the air, provided standard defibrillation precautions are observed.

Critical points:

- The close quarters, metallic environment, and the proximity of electronic equipment do not make helicopters the ideal place for discharging large amounts of stored electrical energy.
- Transient electrical current leakage from commonly used portable defibrillators was measured. A maximum of 1.5 mA was measured which is well within the accepted safety standard of 50 mA.

- Defibrillations were made in flight, to observe avionics and medical equipment interference. No interferences were observed.
- Study concluded that defibrillation can be performed safely on aircraft with normal defibrillation precautions.

Performance of an Automated External Defibrillator during Simulated Rotor-wing Critical Care Transports

Published in *Resuscitation*, 2011.
DOI: 10.1016/j.resuscitation.2010.11.027

By Je, S. M., You, J. S., Chung, T. N., Park, Y. S., Chung, S. P., & Park, I. C.

Abstract: Objective: This study aimed to evaluate whether an AED was accurate enough to analyze the heart rhythm during a simulated rotor wing critical care transport. We hypothesized that AED analysis of the simulated rhythms during a helicopter flight would result in significant errors (i.e., inappropriate shocks, analysis delay). Methods: Three commercial AEDs were tested for analyzing the heart rhythm in a helicopter using a manikin and a human volunteer. Ventricular fibrillation (VF), sinus rhythm, and asystole were simulated by using an arrhythmia simulator of the manikin. The intervals from analysis to shock recommendation were collected on a stationary and in-motion helicopter. Sensitivity and specificity of three AEDs were also calculated. Vibration intensities were measured with a digital vibration meter placed on the chest of the manikin/human volunteer both on the stretcher and on the floor of the helicopter. Results: All AEDs correctly recommended shock delivery for the cardiac rhythms of the manikin. Sensitivity for VF was 100.0% (95% CI 91.2 - 100.0) and specificity for sinus rhythm and asystole were 100.0% (95% CI 91.2 - 100.0). Although the recorded ECG rhythms of the volunteer in an in-motion helicopter showed baseline artifacts, all AEDs analyzed the cardiac rhythm of the volunteer correctly and did not recommend shock delivery. On the floor of the helicopter, the median measured vibration intensity was 6.6 m/s^2 (interquartile range [IQR] 5.5 - 7.7 m/s^2) with significantly less vibrations transmitted to the manikin/human volunteer chest (manikin median 3.1 m/s^2, IQR 2.2 - 4.0 m/s^2; human volunteer median 0.95 m/s^2, IQR 0.65 - 1.25 m/s^2). Conclusion: This study suggested that current AEDs could analyze the heart rhythm correctly during simulated helicopter transport. Further studies using an animal model would be needed before applying to patients.

Critical points:

- This study aimed to evaluate whether an AED was accurate enough to analyze the heart rhythm during a simulated rotor wing critical care transport.
- All AEDs correctly recommended shock delivery for the cardiac rhythms of the manikin. Sensitivity for VF was 100.0% (95% CI 91.2 - 100.0) and specificity for sinus rhythm and asystole were 100.0% (95% CI 91.2 - 100.0).
- Although the recorded ECG rhythms of the human in an in-motion helicopter showed baseline artifacts, all AEDs analyzed the cardiac rhythm of the volunteer correctly and did not recommend shock delivery.

- The median measured vibration intensity was 6.6 m/s^2 (IQR 5.5 - 7.7 m/s^2) with significantly less vibrations transmitted to the manikin/human volunteer chest (manikin median 3.1 m/s^2, IQR 2.2 - 4.0 m/s^2; human volunteer median 0.95 m/s^2, IQR 0.65 - 1.25 m/s^2).

Oxygen Saturation

A Review on Wearable Photoplethysmography Sensors and Their Potential Future Applications in Health Care

Published in I*nternational Journal of Biosensors and Bioelectronics*, 2018.
DOI: 10.15406/ijbsbe.2018.04.00125

By Castaneda, D., Esparza, A., Ghamari, M., Soltanpur, C., & Nazeran, H.

Abstract: PPG is an uncomplicated and inexpensive optical measurement method that is often used for heart rate monitoring purposes. PPG is a non-invasive technology that uses a light source and a photodetector at the surface of skin to measure the volumetric variations of blood circulation. Recently, there has been much interest from numerous researchers around the globe to extract further valuable information from the PPG signal in addition to heart rate estimation and pulse oximetry readings. A PPG signal's second derivative wave contains important health-related information. Thus, analysis of this waveform can help researchers and clinicians to evaluate various cardiovascular-related diseases such as atherosclerosis and arterial stiffness. Moreover, investigating the second derivative wave of a PPG signal can also assist in early detection and diagnosis of various cardiovascular illnesses that typically appear later in life. For early recognition and analysis of such illnesses, continuous and real-time monitoring is an important approach that has been enabled by the latest technological advances in sensor technology and wireless communications. The aim of this article is to briefly consider some of the current developments and challenges of wearable PPG-based monitoring technologies and then to discuss some of the potential applications of this technology in clinical settings.

Critical points:

- Photoplethysmography, known most commonly as PPG, utilizes an infrared light and photodetector to measure the volumetric variations of blood circulation.
- Physical activities and body movements may result in the displacement of the sensor relative to its original location. The sensor movement changes the path of light and consequently modifies the signals. The pressure applied by the device on the skin controls the magnitude of the received signal.
- Motion artifact is disruptive enough that some devices use data from accelerometers to aide algorithms in removing motion artifacts from the PPG signal.

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Pulse Oximetry: Basic Principles and Applications in Aerospace Medicine

Published in *Aviation Space and Environmental Medicine*, 2007.
DOI:

By Wagner, J. L., & Ruskin, K. J.

Abstract: Introduction: Pulse oximeters are reliable, objective, and noninvasive monitors that have broad application in aerospace medicine. New technology enables pulse oximeters to perform well in adverse environments and measure additional parameters. Small, battery-powered devices can be used to monitor oxyhemoglobin saturation while in flight. Theory of Operation: Pulse oximeters use spectrophotometry to measure the ratio of oxyhemoglobin (HbO_2) to reduced hemoglobin (Hb) in arterial blood. This value is displayed as oxyhemoglobin saturation (SpO_2). A Plethysmographic waveform that resembles arterial waveform is also frequently displayed and may indicate relative changes in perfusion and blood volume. Loss and subsequent reappearance of this waveform during occlusion with a cuff has been used to measure systolic blood pressure during helicopter flight. Applications: Accurate determination of oxygen saturation requires a high quality arterial signal and is limited by errors resulting from calibration, motion and vibration, and dyshemoglobinemias. Vasoconstriction may result in decreased pulse amplitude and also impair accurate measurement. Conventional fingertip probes may interfere with the performance of required duties, while helmets and other restrictive clothing can impede the use of sensors on the forehead or ear. Recently introduced devices answer some of these limitations and enable measurement of additional parameters. For example, new probe designs permit more freedom of movement and include a contactless camera and a sensor that fits around a finger like an ordinary ring. This article explains the theory of operation and limitations of pulse oximetry, offers an update on new technology, and discusses applications of this technology in aerospace medicine.

Critical points:

- Pulse oximeters in current use were originally designed to be used as a patient monitor in a setting without bright lights, motion, or other conditions that may impede measurement. As a result, signal extraction algorithms in current use may not work well in aviation or other hostile environments. Bright light, vibration, acceleration, and motion artifact can significantly decrease accuracy.
- Any factor that is not accounted for in the mathematical model may potentially interfere with SpO_2 determination. Such factors may include poor perfusion states, excessive ambient light, motion, and dyshemoglobinemias.
- Excessive ambient light or electromagnetic interference may cause artifact. Sources of ambient light include sunlight and fluorescent light, both of which may be present in aircraft.
- Colored nail polish and intravenous dyes may impair accurate measurement of SpO_2.
- Pulse oximeters typically display an artificially decreased SpO_2 when the subject moves.

Pulse Oximetry during Helicopter Transport
Published in *Air Medical Journal*, 1993.
DOI: 10.1016/S1067-991X (05)80149-X

By DeJarnette, R., Holleran, R., Von Rotz, N. P., Downing, C., Willhite, J., & Storer, D.

Abstract: The study objective was to determine if pulse oximetry readings obtained during helicopter transport were indicative of subsequent arterial blood-gas measured saturations. A prospective study design was chosen. Data were gathered on a convenience sample of patients 18 years and older not under cardiopulmonary resuscitation; 101 patients were used for the study. Pulse oximeter readings of oxygen saturation and heart rate were recorded along with simultaneous vital signs. Arterial saturation in blood gases drawn in the emergency department were added to the patient record. Improper functioning of the pulse oximeter was recorded on 10 (9.9%) of the patients. No correlation was found between the probe type and the documented problems (Phi coefficient= 0.009). The pulse oximeter saturation readings were not significantly different from arterial saturation in blood gases when compared by paired samples t-test ($t = 0.880$, $p = 0.383$). There was also no significant difference between the patient's heart rate sensed by the pulse oximeter and the simultaneous palpated pulse rate. Percent saturation readings by repeated measures were statistically different ($p < 0.05$) showing a minimal improvement in saturation over time. Based on this study's findings, the authors feel the pulse oximeter can be a valuable adjunct to patient care during helicopter transport.

Critical points:

- Improper functioning of the pulse oximeter was recorded on 10 (9.9%) of the patients, reasons unknown.
- Environmental factors such as noise, temperature, lighting, and vibration can impede assessment.

Human Vital Signs Detection Methods and Potential Using Radars: A Review
Published in *Sensors*, 2020.
DOI: 10.3390/s20051454

By Kebe, M., Gadhafi, R., Mohammad, B., Sanduleanu, M., Saleh, H., & Al-Qutayri, M.

Abstract: Available above in the Electrocardiogram and Defibrillation section.

Critical points:

- Oxygen saturation is measured using PPG.
- PPG systems most often produce signals that are affected by several factors including the measuring site, ambient temperature, and the posture of the subject.
- The accuracy of the PPG raw signal can be undermined by the motion artifact of the subject.

Photoplethysmograph Signal Reconstruction Based on a Novel Hybrid Motion Artifact Detection-Reduction Approach Part I: Motion and Noise Artifact Detection

Published in *Annals of Biomedical Engineering*, 2014.
DOI: 10.1007/s10439-014-1080-y

By Chong, J. W., Dao, D. K., Salehizadeh, S. M. A., McManus, D. D., Darling, C. E., Chon, K. H., & Mendelson, Y.

Abstract: Motion and noise artifacts (MNA) are a serious obstacle in utilizing PPG signals for real-time monitoring of vital signs. We present an MNA detection method which can provide a clean versus corrupted decision on each successive PPG segment. For motion artifact detection, we compute four time-domain parameters: (1) standard deviation of peak-to-peak intervals, (2) standard deviation of peak-to-peak amplitudes, (3) standard deviation of systolic and diastolic interval ratios, and (4) mean standard deviation of pulse shape. We have adopted a support vector machine (SVM) which takes these parameters from clean and corrupted PPG signals and builds a decision boundary to classify them. We apply several distinct features of the PPG data to enhance classification performance. The algorithm we developed was verified on PPG data segments recorded by simulation, laboratory-controlled and walking/stair-climbing experiments, respectively, and we compared several well-established MNA detection methods to our proposed algorithm. All compared detection algorithms were evaluated in terms of motion artifact detection accuracy, heart rate error, and SpO_2 error. For laboratory controlled finger, forehead recorded PPG data and daily-activity movement data, our proposed algorithm gives 94.4, 93.4, and 93.7% accuracies, respectively. Significant reductions in HR and SpO_2 errors (2.3 beats per minute [bpm] and 2.7%) were noted when the artifacts that were identified by SVM-MNA were removed from the original signal than without (17.3 bpm and 5.4%). The accuracy and error values of our proposed method were significantly higher and lower, respectively, than all other detection methods. Another advantage of our method is its ability to provide highly accurate onset and offset detection times of MNAs. This capability is important for an automated approach to signal reconstruction of only those data points that need to be reconstructed, which is the subject of the companion paper to this article. Finally, our MNA detection algorithm is real-time realizable as the computational speed on the 7-s PPG data segment was found to be only 7 milliseconds (ms) with a MATLAB code.

Critical points:

- Photoplethysmography for monitoring HR and SpO_2 is susceptible to motion artifact and noise artifact.
- There are three distinct sources of MNA that can distort PPG recordings: environmental, physiological and experimental artifacts, which can be attributed to (1) electromagnetic and power interference around the body, (2) cross talk pickup of other physiological signals, and (3) instrumental noise, respectively.

Real alerts and Artifact Classification in Archived Multi-signal Vital Sign Monitoring Data: Implications for Mining Big Data

Published in *Journal of Clinical Monitoring & Computing*, 2016.
DOI: 10.1007/s10877-015-9788-2

By Hravnak, M., Chen, L., Dubraswski, A., Bose, E., Clermont, G., & Pinsky, M.

Abstract: Huge hospital information system databases can be mined for knowledge discovery and decision support, but artifact in stored non-invasive vital sign (VS) high-frequency data streams limits its use. We used machine-learning (ML) algorithms trained on expert-labeled VS data streams to automatically classify VS alerts as real or artifact, thereby ‘‘cleaning’’ such data for future modeling. Six hundred thirty four admissions to a step-down unit had recorded continuous noninvasive VS monitoring data (HR, RR, and SpO_2 at 1/20 hertz [Hz], and noninvasive oscillometric BP). Time data were across stability thresholds defined VS event epochs. Data were divided Block 1 as the ML training/cross-validation set and Block 2 the test set. Expert clinicians annotated Block 1 events as perceived real or artifact. After feature extraction, ML algorithms were trained to create and validate models automatically classifying events as real or artifact. The models were then tested on Block 2. Block 1 yielded 812 VS events, with 214 (26 %) judged by experts as artifact (RR 43 %, SpO_2 40 %, BP 15 %, HR 2 %). ML algorithms applied to the Block 1 training/cross-validation set (tenfold cross-validation) gave area under the curve (AUC) scores of 0.97 RR, 0.91 BP, and 0.76 SpO_2. Performance when applied to Block 2 test data was AUC 0.94 RR, 0.84 BP, and 0.72 SpO_2. ML-defined algorithms applied to archived multi-signal continuous VS monitoring data allowed accurate automated classification of VS alerts as real or artifact, and could support data mining for future model building.

Critical points:

- HR Artifact Rule 1: A step increase or decrease in HR to a stable new state and a step decrease back to the same state with no change in other variables. This signal usually generates a new plateau, causing a square wave pattern. Cause may be patient movement leading to change in lead sensitivity doubling the R wave count.
- SpO_2 Artifact Rule 1: Loss of signal which is intermittent, without accompanying changes in other vital signs. Cause may be loose lead or patient movement.
- SpO_2 Artifact Rule 2: Initial reading of low SpO_2 following absence of signal (IF) absence of the SpO_2 signal is also accompanied by absence of all other parameter signals.
- SpO_2 Artifact Rule 3: SpO_2 signal has abrupt step increase or decrease with no changes in HR or RR. Cause may be sensor losing contact and re-contacting.

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Respiratory Rate, End-Tidal CO_2, and Ventilation Rate

Recent Development of Respiratory Rate Measurement Technologies

Published in *Physiological Measurement*, 2019.
DOI: 10.1088/1361-6579/ab299e

By Lui, H., Allen, J., Zheng, D., & Chen, F.

Abstract: RR is an important physiological parameter whose abnormality has been regarded as an important indicator of serious illness. In order to make RR monitoring simple to perform, reliable, and accurate, many different methods have been proposed for such automatic monitoring. According to the theory of respiratory rate extraction, methods are categorized into three modalities: extracting RR from other physiological signals, RR measurement based on respiratory movements, and RR measurement based on airflow. The merits and limitations of each method are highlighted and discussed. In addition, current works are summarized to suggest key directions for the development of future RR monitoring methodologies.

Critical points:

- RR can be captured by extracting RR from other physiological signals, measurement based on respiratory movements, and measurement based on airflow.
- There are significant respiratory influences on physiological signals such as ECG, PPG, ballistocardiogram, seismocardiogram, oscillometric cuff pressure pulses, and Korotkoff sounds, which algorithms can use to derive respiratory rate.
- Volume changes in the thoracic and abdominal areas during respiration can be detected by accelerometers, gyrometers, radars and WiFi devices, imaging, and various sensors based on electromagnetic, piezoresistive, piezoelectric, and optical mechanisms.
- Respiratory airflow causes periodic fluctuations in temperature, humidity, density of carbon dioxide, and sound.
- Measurement of RR based on other vital signs depends on the accuracy of those measurements. Environmental noise affects acoustic, thermal, and oscillometric methods. Motion artifact affects nearly all methods.

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Real alerts and Artifact Classification in Archived Multi-signal Vital Sign Monitoring Data: Implications for Mining Big Data
Published in *Journal of Clinical Monitoring & Computing,* 2016.
DOI: 10.1007/s10877-015-9788-2

By Hravnak, M., Chen, L., Dubraswski, A., Bose, E., Clermont, G., & Pinsky, M.

Abstract: Available above in the Oxygen Saturation section.

Critical points:

- RR artifact Rule 1: The presence of a RR signal in the absence of a HR signal is an artifact. No ECG signal is the root cause of the erroneous pleth signal.
- RR artifact Rule 2: Poor signal capture of the impedance—a step increase and decrease—wide changes, cyclical, oscillatory-like. As such, the value of the RR is incalculable. Instantaneous oscillatory step increase up and down of > 30 breaths a minute. This artifact can give us some information; it might indicate that the patient is agitated or that there is sweat under the electrode. Cause may be patient movement.

The artifacts of Human Physical Motions on Vital Signs Monitoring
Published in *2019 Scientific Meeting on Electrical-Electronics & Biomedical Engineering and Computer Science (EBBT),* 2019.
DOI: 10.1109/EBBT.2019.8741668

By Eren, C., Karamzadeh, S., & Kartal, M.

Abstract: In this study, we aim to analyze effects of physical motions of human body such as hand movements and speaking during contactless vital signs monitoring. Human RR has periodic in nature and its frequency varies between 0.2 - 0.5Hz for each human. Considering weakness of human vital signs, the analysis of other physical movements of human body on vital signs monitoring should well analyzed to obtain accurate RR results. This situation carries great significance in health-care units which purpose the non-contact and non-invasive monitoring of patients in near future. In order to achieve our goal, an ultrawide band (UWB) radar system has been used to detect respiratory rate of human body. Mathematical model of human breath signal and theoretical analysis of RR detection using UWB radar has been explained. The spectral estimation of RR has been performed by Fast Fourier Transform (FFT) due to its rapid response and simplicity. The strong noise effects of such physical movements of human body during RR monitoring have been observed and results are presented.

Critical points:

- Study examined how physical motions of human body affected respiratory rate being monitored by radar techniques.
- Talking and moving hands could affect the signal to noise ratios.
- Endemic movement of the environment likely to cause the same noise issue.

Human Vital Signs Detection Methods and Potential Using Radars: A Review
Published in *Sensors*, 2020.
DOI: 10.3390/s20051454

By Kebe M., Gadhafi R., Mohammad B., Sanduleanu M., Saleh H., & Al-Qutayri M.

Abstract: Available above in Electrocardiogram and Defibrillation section and Respiratory Rate, End-Tidal CO_2 and Ventilation Rate section.

Critical points:

- Capnography measures the difference in CO_2 levels between inhalation and exhalation using chemical sensors to determine the breath rate.
- Despite their insensitivity to the motion artifact of the subject, breath rate measurement based on capnography is quite uncomfortable for long-term monitoring and can be very sensitive to other gas components and changes in humidity and temperature of the environment. It is not sensitive to patients, but the environment. Good for ruling out errors.
- Thermistors are also used to measure breath rate. Requires a mask. No mentioned errors.
- Breath rate can also be measured using humidity sensors. Requires a mask. No mentioned errors.

Effectiveness of Manual Ventilation in Intubated Helicopter Emergency Services–Transported Trauma Patients
Published in *Air Medical Journal*, 2019.
DOI: 10.1016/j.amj.2019.03.013

By McLachlan, B., Bilbrey, C., Mausner, K., & Lenz, T. J.

Abstract: Background: Helicopter Emergency Medical Services (HEMS) agencies frequently transport intubated patients to definitive care. No evidence exists to determine the type of ventilation in this population. Practice varies amongst programs from bag-valve-mask to mechanical ventilation. Study Objective: Evaluate the effectiveness of bag-valve ventilation in intubated trauma patients. We hypothesized manual ventilation provides adequate support to maintain physiologic $ETCO_2$. Methods: From June to December 2015, twenty patients were enrolled in this prospective, observational study. Included were endotracheally intubated trauma patients transported by this HEMS program. Excluded were interfacility transports, non-scene calls, and patients with supraglottic devices. $ETCO_2$ was recorded every 30 seconds during the flight. As a descriptive pilot study, power was not considered. Results: Twenty patients provided over 500 cumulative minutes of manual ventilation data. The percentage of cumulative time spent with adequate oxygen saturations was 83.6%. The percentage of cumulative time spent with adequate $ETCO_2$ was 48.7%, with 34.6% of time spent under and 16.7% above this range. Conclusion: Manual ventilation maintained a physiologic $ETCO_2$ only 16.7% of the time. Significant variability existed, resulting in intermittent hypoxia and

hyperventilation. Prior research linked such events to increased morbidity and mortality. Further studies are warranted to compare manual against mechanically ventilated patients.

Critical points:

- Twenty patients being incubated during helicopter and $ETCO_2$ was recorded every 30 seconds during the flight.
- The data shows that appropriate oxygenation is provided most of the time, but many would argue that adequate oxygenation 83.6% of the time is simply not acceptable.
- The instances of hypoxia could be explained by significant lung injuries because all patients in this study group suffered blunt trauma resulting in intubation.
- The data do not seem to suggest a problem with oxygenation but rather a problem with ventilation.
- Significant variability existed, resulting in intermittent hypoxia and hyperventilation.

Evaluation of Transport Ventilators at Mild Simulated Altitude: A Bench Study in a Hypobaric Chamber

Published in *Respiratory Care*, 2014.
DOI: 10.4187/respcare.02985

By Boussen, S., Coulange, M., Fournier, M., Gainnier, M., Michelet, P., Micoli, C., & Negrel, L.

Abstract: Background: Previous studies on ventilators used for air transport showed significant effects of altitude, in particular with regard to accuracy of the tidal volume (V_T) and breathing frequency. The aim of the study was to evaluate transport ventilators under hypobaric conditions. Methods: We conducted a bench study of 6 transport ventilators in a Comex hypobaric chamber to simulate mild altitude (1500 meters [m] [4920 feet] and 2500 m [8200 feet]). The ventilators were connected to a test lung to evaluate their accuracy: (1) to deliver a set V_T under normal resistance and compliance conditions at fraction of inspired oxygen (F_iO_2) = 0.6 and 1, (2) to establish a set positive end expiratory pressure (PEEP) (0, 5, 10, and 15 cm H2O), and (3) to establish a set inspiratory pressure in pressure controlled mode, (4) at a F_iO_2 setting, and (5) and at a frequency setting. Results: Four ventilators kept an average relative error in V_T of < 10% without effect of altitude. The Medumat ventilator was affected by the altitude only at F_iO_2 = 1. The Osiris 3 ventilator had > 40% error even at 1500 m. We found no change in frequency as a function of altitude for any ventilators studied. No clinically important differences were found between all altitudes with the PEEP or inspiratory pressure setting. Although F_iO_2 was affected by altitude, the average error did not exceed 11%, and it is unclear whether this fact is an experimental artifact. Conclusions: We have shown that most of the new transport ventilators tested require no setting adjustment at moderate altitude and are as safe at altitude as at sea level under normal respiratory conditions. Older technologies still deliver more volume with altitude in volumetric mode.

Critical points:

- Evaluated ventilators under hypobaric conditions by measuring tidal volume and breathing frequencies.
- Four out of the six ventilators kept an average error in tidal volumes of less than 10% without effect of altitude.
- Other ventilators have an error of greater than 40% at altitude.
- No changing in breathing frequencies were found between altitudes.

Blood Pressure

Prehospital Blood Pressures: Inaccuracies Caused by Ambulance Noise
Published in *American Journal of Emergency Medicine*, 1994.
DOI: 10.1016/0735-6757(94)90025-6

By Prasad, N. H., Brown, L. H., Ausband, S. C., Cooper-Spruill, O., Carroll, R. G., & Whitley, T. W.

Abstract: Blood pressure measurements in a moving ambulance can be difficult to obtain. Sirens, engine noise, and road noise can all interfere with the accurate detection of patient's blood pressure. This study was under-taken to determine the influence of ambulance noise and vibration on auscultated blood pressures. A model was developed that used dynamic pressures to simulate systolic Korotkoff sounds. Forty-nine emergency personnel were asked to obtain blood pressures using the model in both a quiet environment and in a moving ambulance. A total of 485 blood pressure measurements were obtained. Systolic pressures were randomized to two settings: 76 millimetres of mercury (mmHg) and 138 mmHg. Stationary readings were compared with moving readings using analysis of variance for repeated measures. Systolic blood pressure measurements obtained in the quiet environment averaged 133 ± 5 mmHg at the high setting, and 45 ± 6 mmHg at the low setting. Systolic blood pressure measurements obtained in a moving ambulance averaged 86 ± 7 mmHg at the high setting, and 41 ± 7 mmHg at the low setting. The average differences between quiet and moving measurements were 47 mm Hg at the "high" setting ($P < .01$) and 4 mmHg at the "low" setting ($P > .01$). At physiological levels, blood pressures obtained in moving ambulances differ significantly from those obtained in a quiet environment, which may be caused by road noise and ambulance motion.

Critical points:

- It is recognized that indirectly measured, or auscultated, blood pressures often differ from directly measured arterial pressures. It is believed that the noise and motion artifact associated with transportation in an ambulance can exacerbate this difference.
- This study is the first to compare blood pressures auscultated in a moving ambulance to a known, directly measured pressure.

- The major finding of this study is the large difference between blood pressures auscultated in a quiet environment and those obtained in a moving ambulance when the model was set at a physiological level.
- This study suggests that blood pressure readings obtained in moving ambulances are adversely affected by road noise and motion artifact. Sirens, radio noise, air conditioners, and suction units may further affect auscultated blood pressures.
- The model skin was not human and probably did not transmit sound as a human arm would. The fluid used in this model was not human blood. The pump used to circulate the fluid, although encased in an insulated box, did create some noise.

Real Alerts and Artifact Classification in Archived Multi-signal Vital Sign Monitoring Data: Implications for Mining Big Data
Published in *Journal of Clinical Monitoring & Computing*, 2016.
DOI: 10.1007/s10877-015-9788-2

By Hravnak M., Chen L., Dubraswski A., Bose E., Clermont G., & Pinsky M.

Abstract: Available above in the Oxygen Saturation section and the Respiratory Rate, End-Tidal CO_2 and Ventilation Rate section.

Critical points:

- BP Artifact Rule 1: Immediate decrease in pulse pressure (PP) (PP = SBP-DBP) to 30 mmHg or less. DBP increases with PP drop while SBP remains the same or high. This artifact is from the patient but is not correctly measured. This type of artifact might represent patient agitation and as such might be an independent measure of instability.
- BP Artifact Rule 2: Immediate step increase in systolic blood pressure (SBP), mean and diastolic blood pressure (DBP). Rise in DBP values close to SBP, PP minimal to nonexistent. This type of artifact may also represent patient movement or tensing arm.
- BP Artifact Rule 3: If measurement is repeated, signal returns to normal patterns. The initial BP on startup may be inaccurate, if a repeat reading is done in the first 30 minutes, then we ignore the first reading. This type of artifact may also represent patient movement or tensing arm.

Measurement of Systolic Blood Pressure using Pulse Oximetry during Helicopter Flight
Published in *Critical Care Medicine*, 1991.
DOI: 10.1097/00003246-199107000-00018

By Talke, P. O.

Abstract: Objective: Monitoring of vital signs in critically ill patients during helicopter flight is difficult because of the noise and vibrations of the aircraft. We evaluated the use of a pulse oximeter to measure systolic BP intraflight. Design: Systolic BP measured by pulse oximetry was compared with systolic BP measured by the direct intra-arterial and the

arterial occlusion methods intraflight. Systolic BP by pulse oximetry was measured by observing the return of the plethysmographic waveform of the pulse oximeter as the BP cuff ipsilateral to the pulse oximeter probe was slowly deflated. Arterial occlusion pressure was measured by observing the return of the intra-arterial waveform as the BP cuff ipsilateral to the arterial cannula was slowly deflated. Setting: The study was performed during patient transport, intraflight. Patients: Ten critically ill patients were studied. Interventions: None. Measurements and Main Results: Seventy-three sets of measurements were recorded. The best correlation (r^2 = .99) was found between pulse oximetry and the arterial occlusion method. The indirect methods correlated better with each other than with direct intra-arterial measurements. The noise and the vibrations of the helicopter did not significantly interfere with the operation of the pulse oximeter. Conclusions: We conclude that a pulse oximeter that displays a plethysmographic waveform can accurately measure systolic BP intraflight.

Critical points:

- Since pulse oximeters use emitted light to collect information and display the data visually, there is minimal interference from the noise or vibrations of the helicopter.
- None of our patients were hypotensive, cold, or received significant quantities of vasopressors, all of which could decease peripheral perfusion and make it more difficult for the pulse oximeter to obtain and adequate signal.
- It is expected that pulse oximetry, as well as most other methods of BP measurement, would fail on trauma victims with poor perfusion.
- In conclusion, our results indicate that in addition to providing valuable information on arterial oxygen saturation (SaO_2), the pulse oximeter can be used to measure systolic BP during helicopter flight.

Comparison of Non-Invasive and Invasive Blood Pressure in Aeromedical Care
Published in *Anaesthesia*, 2012.
DOI: 10.1111/j.1365-2044.2012.07302.x

By McMahon, N., Hogg, L. A., Corfield, A. R., & Exton, A. D.

Abstract: Blood pressure measurement is an essential physiological measurement for all critically ill patients. Previous work has shown that non-invasive blood pressure is not an accurate reflection of invasive blood pressure measurement. In a transport environment, the effects of motion and vibration may make non-invasive blood pressure less accurate. Consecutive critically ill patients transported by a dedicated aeromedical retrieval and critical care transfer service with simultaneous invasive and non-invasive blood pressure measurements were analyzed. Two sets of measurements were recorded, first in a hospital environment before departure (pre-flight) and a second during aeromedical transport (in-flight). A total of 56 complete sets of data were analyzed. Bland-Altman plots showed limits of agreement (precision) for pre-flight systolic blood pressure were -37.3 mmHg to 30.0 mmHg, and for pre-flight mean arterial pressure -20.5 mmHg to 25.0 mmHg. The limits of agreement for in-flight systolic blood pressure were -40.6 mmHg to 33.1 mmHg,

while those for in-flight mean blood pressure in-flight were -23.6 mmHg to 24.6 mmHg. The bias for the four conditions ranged from 0.5 to -3.8 mmHg. There were no significant differences in values between pre-flight and in-flight blood pressure measurements for all categories of blood pressure measurement. Thus, our data show that non-invasive blood pressure is not a precise reflection of invasive intra-arterial blood pressure (IABP). Mean blood pressure measured non-invasively may be a better marker of invasive blood pressure than systolic blood pressure. Our data show no evidence of non-invasive blood pressures being less accurate in an aeromedical transport environment.

Critical points:

- Due to motion and vibration in a transport environment, non-invasive blood pressure is less accurate.
- Bland-Altman plots shows limits of agreement for pre-flight systolic blood pressure were -37.3 mmHg to 30.0 mmHg and pre-flight mean arterial pressure -20.5 mmHg to 25.0 mmHg.
- Systolic blood pressure inflight were -40.6 mmHg to 33.1 mmHg and in-flight mean blood pressure -23.6 mmHg to 24.6 mmHg.
- This may reflect improved technology within NIBP monitoring devices or newer aircraft causing less vibration on the patient or monitoring system.
- IABP should be used on crucially ill patients where accurate blood pressure is desired.

Formulas to Explain Popular Oscillometric Blood Pressure Estimation Algorithms
Published in *Frontiers in Physiology*, 2019.
DOI: 10.3389/fphys.2019.01415

By Chandrasekhar, A., Yavarimanesh, M., Hahn, J., Sung, S., Chen, C., Cheng, H., & Mukkamala, R.

Abstract: Oscillometry is the BP measurement principle of most automatic cuff devices. The oscillogram (which is approximately the blood volume oscillation amplitude-external pressure function) is measured, and BP is then estimated via an empirical algorithm. The objective was to establish formulas to explain three popular empirical algorithms in the literature—the maximum amplitude, derivative, and fixed ratio algorithms. A mathematical model of the oscillogram was developed and analyzed to derive parametric formulas for explaining each algorithm. Exemplary parameter values were obtained by fitting the model to measured oscillograms. The model and formulas were validated by showing that their predictions correspond to measurements. The formula for the maximum amplitude algorithm indicates that it yields a weighted average of systolic and diastolic BP (0.45 and 0.55 weighting) instead of commonly assumed mean BP. The formulas for the derivative algorithm indicate that it can accurately estimate systolic and diastolic BP (<1.5 mmHg error), if oscillogram measurement noise can be obviated. The formulas for the fixed ratio algorithm indicate that it can yield inaccurate BP estimates, because the ratios change substantially (over a 0.5 - 0.6 range) with arterial compliance and pulse pressure and error in the assumed ratio translates to BP error via large amplification (> 40). The established formulas allow for easy and complete interpretation

of perhaps the three most popular oscillometric BP estimation algorithms in the literature while providing new insights. The model and formulas may also be of some value toward improving the accuracy of automatic cuff BP measurement devices.

Critical points:

- Oscillometry is the BP measurement methodology of most automatic cuff devices.
- The external pressure of an artery is swept between supra-systolic and sub-diastolic BP levels, the external pressure is measured and high-pass filtered to yield oscillations indicative of the blood volume, and the BP is estimated via algorithm.
- Movements associated with respiration, heart rate variability, and vehicle motion can introduce error into the sensing of the pressure pulses.
- Algorithms often rely on differentiation which amplifies measurement noise.

Noninvasive Blood Pressure Performance: A Reproducible Method for Quantifying Motion Artifact in Oscillometry

Published in *Biomedical Instrumentation and Technology*, 2001.
DOI: (n/a)

By Van Horn, R. H., Kahlke, R. J., Taylor, L. A., & Dorsett, T. J.

Abstract: Motion artifact tends to degrade oscillometric NIBP accuracy and other aspects of performance (measurement time, patient comfort, false-positive readings). Medical personnel generally have not fully appreciated the extent of these degradations, in part because NIBP provides no waveform display to allow visualization of artifact disruption (unlike the ECG and SpO_2 patient channels). More importantly, the magnitude and frequency of NIBP errors has also gone unappreciated because the auditory noise produced by transport vibration prevents accurate quantification of NIBP accuracy by the traditional auscultatory method. To overcome these problems, a commercially available NIBP simulator was modified to permit the superimposition of repeatable motion artifact waveforms from a function generator onto known patient blood pressure profiles available in the NIBP simulator. The superimposed artifact waveforms had been collected under transport conditions. This methodology enabled comparisons between artifact-free NIBP readings, on the one hand, and artifact-contaminated readings on the other. Monitors under test were subjected to multiple combinations of patient and artifact profiles. Measurement errors were expressed as a percent deviation of the artifact-contaminated readings from the expected (artifact-free) readings. Statistical analyses of the data compared the performance of the different monitor types with nonparametric tests of inference (Kruskal-Wallis H test, Mann-Whitney U test, and chi-squared test). These analyses demonstrated statistically significant differences in performance including accuracy, yield (incidence of values within various error categories), retries, measurement time, and false-positive readings under artifact-only conditions. The method further demonstrated that the monitor using ECG synchronization to filter motion artifact achieved statistically and clinically significant improvements in accuracy without compromising clinical expectations for

measurement time. This approach provided a reproducible and quantifiable method by which to assess and differentiate the artifact tolerance of different NIBP technologies.

Critical points:

- Medical personnel tend to underestimate the number of errors inherent in oscillometric measurement of blood pressure measurement due to the lack of a continuous waveform that visually represents breaks in measurement.
- The paper describes a blood pressure simulator that permits imposition of motion artifacts on generated waveforms.

A procedure for Evaluation of Non-Invasive Blood Pressure Simulators
Published in *Medical & Biological Engineering & Computing*, 2009.
DOI: 10.1007/s11517-009-0532-2

By Gersak, G., Zemva, A., & Drnovsek, J.

Abstract: NIBP simulators are used in clinical environment for quick checks of blood pressure monitors as a part of technical maintenance and health-care quality assurance system. They are also included in various tests within the procedures for testing NIBP monitors. In practice simulators are often subject to mechanical and electromagnetic shocks which could affect their measuring function. Our objective was to design a procedure for testing the reliability and quality of simulators in order to ensure reliable testing of NIBP monitors. Procedure for evaluation of NIBP simulators, consisting of a static and dynamic test, is proposed. Static test consisted of procedures derived from common electro-mechanical manometer calibration, while dynamic test included testing of repeatability of simulator's output. A commercial simulator was tested. Among others, the results indicated that evaluations of NIBP simulators should be performed regularly with a suitable time interval in order to track the metrological quality of the simulator in time. Acceptance criteria for a reliable simulator in both static and dynamic sense are proposed.

Critical points:

- Waveform simulators are not capable of taking into account the transfer function between arterial pressure in the limb, air pressure in the cuff, the effects of cuff bladder size, placement of the cuff, or the material from which the cuff is made.
- These variables could only be assessed by performing clinical validation on human subjects, since currently available commercial waveform simulators are not able to replay realistic human signals.

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Evaluating the Impact of Motion Artifact on Noninvasive Blood Pressure Devices
Published in *Journal of Clinical Hypertension*, 2020.
DOI: 10.1111/jch.13851

By Alpert, B. S., Quinn, D. E., Friedman, B. C., Matsumura, P. M., Dart, R. A., & Donehoo, R. F.

Abstract: Most automated sphygmomanometers use oscillometric algorithms. Motion, either patient-based or environmental, will affect the ability of a device to record an accurate BP. Members of the Association for the Advancement of Medical Instrumentation (AAMI) Sphygmomanometer Committee have been studying this problem for more than a decade. The AAMI TIR44 was the first publication to address the challenges of motion tolerance. The concepts described in TIR44 have led to the development of a draft of ISO 81060-4, a new standard for testing devices for which the manufacturer wishes to claim motion tolerance. The current ISO 81060-2 addresses both stress testing and 24-hour ambulatory BP monitoring. Recent publications have reported on testing of devices in response to voluntary and involuntary patient motion. The ISO 81060-4 will address testing in the presence of patient transport by ground, fixed-wing, and rotary (helicopter) ambulances. The protocol will utilize noise profiles recorded under those three conditions. The profiles will be digitally stored on a library with free access. The proposed testing will be performed using patient simulators introducing the noise library files into known BP oscillometric envelopes. The specifications of the data capture and playback devices are specified, as is the evaluation statistical testing. The authors expect that the final draft will be published in 2020.

Critical points:

- Motion artifact is a known cause for error during oscillometric measurement of blood pressure. Sources include voluntary and involuntary patient movement, and vehicle motion during transport.
- The study team created a sensorized cuff mandrel system; the mandrel was composed of polyvinyl chloride pipe wrapped with foam with accelerometers and pressure sensors. The blood pressure cuff was wrapped around this device, while the fixture was subject to vehicle rides.
- Procedures form the basis of ISO 81060-4 *Non-invasive sphygmomanometers — Part 4: Requirements for devices intended for use during patient transport*, a standard for testing blood pressure devices that claim tolerance to motion artifacts. This standard is still under development.

Appendix C. Summary of High Vibration Warnings, Cautions, and Notes from ACM

Summary of warnings, cautions, and notes specific to the high vibration environment from *Aeromedical certification memorandum (ACM) for Patient Movement Items (PMI) aboard Army H-60, UH-72, CH-47, and MH Rotary-wing Aircraft (ACM-2018 Revision 3).* This document specifically addresses issues that may affect patient safety when using the medical devices during aeromedical transport.

Warnings:

1. When exposed to heavy vibrations, a "Self-Check Failure" alarm may occur and render the unit momentarily inoperative. Cycling power removes the alarm condition. Care providers should be aware of this potential occurrence and have a big valve mask available during patient transport.

Cautions:

17. Battery may momentarily lose contact with battery connector in high vibration environments.

28. During heavy vibration, it is possible for the filter located inside the canister lid to become stuck in a closed position. By design, this prevents fluid from entering the aspirator. When this occurs, there is no negative suction being applied to the patient.

Notes:

37. Aircraft vibration can cause degraded display legibility in high vibration flight modes.

39. In a high vibration environment, there may be inaccuracies in the respiratory detection feature.

46. The device's default setting for flow trigger sensitivity may need to be adjusted to avoid auto-cycling in a high-vibration environment.

Types of Devices:

- Patient monitors (2)
- Automated external defibrillators (1)
- Combined patient monitor/defibrillators (3)
- Ventilators (2)
- Suction/aspirators (2)

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All of USAARL's science and technical information documents are available for download from the Defense Technical Information Center.

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