European University Cyprus
6 Diogenes Street, 2404 Engomi, Nicosia
P.O.Box 22006, 1516 Nicosia, Cyprus
T: 22713000, F: 22713172, E: info@euc.ac.cy
www.euc.ac.cy

Study Protocol

Assessing the Validity and Reliability of Two IMU Sensor Systems and a Goniometer in Multi-Planar Cervical Motion

Introduction

The head contains the peripheral vestibular system, a vital sensory system that contributes to balance control during both static and dynamic tasks (Hain & Helminski, 2014). Accurate measurement of head posture and cervical range of motion (CROM) is also crucial for understanding spatial orientation and the integration of neural inputs from the semicircular canals and otolith organs, providing valuable insights for designing targeted vestibular rehabilitation strategies (Casado-Sánchez et al., 2025; Horak, 2006). CROM measurement is a key element in rehabilitation, as it informs clinical decisions, monitors patient progress, and supports discharge planning (Norkin & White, 2016). Objective biomechanical evaluation of cervical motion enables the detection of dysfunction and assessment of treatment outcomes, with broad applications in clinical practice, sports performance, ergonomics, and pain management (Haimovich et al., 2021). While extensive research has focused on other joints (Camargo et al., 2021; Rigoni et al., 2019; Scherpereel et al., 2023), cervical motion assessment remains an evolving field with growing relevance in both clinical and research settings (Keidan et al., 2025).

The universal goniometer (UG) is widely used in various clinical settings, including physical therapy clinics, to assess range of motion (ROM) due to its ease of use, speed, and reasonable measurement accuracy (Brosseau et al., 2001; Gajdosik & Bohannon, 1987; Goodwin et al., 1992; Mayerson & Milano, 1984; Tucci et al., 1986). As a result, the UG is considered the gold standard for ROM assessment (Wilson-Smith et al., 2022). However, despite its application in CROM measurement, UG has known limitations in accuracy and reproducibility. It requires trunk stabilisation to ensure pure CROM assessment, restricts measurements to predominantly upright positions, and limits clinicians' ability to evaluate neck CROM in diverse settings or

during complex dynamic activities (Keidan et al., 2025).

The advancement of optical motion capture (MoCap) systems, including both marker-based and markerless technologies, has revolutionised human motion assessment. The marker-based optoelectronic system, widely regarded as the gold standard for human movement analysis, offers high accuracy, rapid data capture, and reliable multi-plane tracking of body segments (Cuesta-Vargas et al., 2010; Kimberlin & Winterstein, 2008). However, its complexity, high cost, time demands, and the need for minimal clothing and highly trained operators limit its use in real-world clinical settings (Cimolin et al., 2022; Miranda et al., 2013; Wade et al., 2022). In contrast, wearable inertial sensors provide a user-friendly, time-efficient alternative that allows clinicians and researchers to collect quantitative data on functional limitations while enhancing ecological validity (Kimberlin & Winterstein, 2008).

Although the assessment of movement using IMU sensors has increased over the past decade, the measurement of angular movements has often proven problematic, with studies showing discrepancies in validity, a limited number of participants, or unreproducible results (Chan et al., 2022; Morrow et al., 2017; Rekant et al., 2022; Seong et al., 2024; Tolza et al., 2017; Wiles et al., 2023; Wong et al., 2015; Yoon et al., 2019).

Aims

Hence, this work aims to assess the validity and reliability of the CROM measurement obtained by two inertial sensor systems in a group of healthy individuals when compared to that obtained by the gold-standard assessment methodology of the UG and using photographic measurements (Yoon et al., 2019). The dataset will support the development of methods that enable the estimation of CROM from raw IMU data through static and functional calibration steps, thereby eliminating the common problem of drift, which most sensor fusion algorithms cannot completely address.

Dealing with and eliminating drift is essential for maintaining accuracy in long-term monitoring and ensuring consistent data quality across various conditions and environments. Robust calibration methods ensure reliability in long-term usage, which is critical in both clinical and real-world settings. Furthermore, if Delsys sensors are employed, an additional benefit is the ability to record electromyographic (EMG) signals simultaneously. This eliminates the need for integrating separate IMU (accelerometer, gyroscope, magnetometer) and EMG systems via third-party data acquisition hardware, thereby streamlining experimental setup and improving data synchronisation (Karatsidis et al., 2017).

Materials and Methods

Participants

The sample size estimation was conducted using G*Power 3.1 (Faul et al., 2007, 2009) to ensure sufficient statistical power for validity assessment. In the present study, with N = 18, the minimum required correlation coefficient to achieve a power level of 0.80 at a significance level of p = 0.05 is 0.67.

The sample will consist of participants without any neck pain, neck-related injuries, or cervical spine conditions in the past few years. Individuals with a history of musculoskeletal or neurological disorders, pain, balance disorders, or other symptoms that may hinder the execution of the tests will be excluded from the study. All participants will be required to sign a written informed consent form that provides a detailed description of the experimental tests. The study will be conducted in accordance with the Declaration of Helsinki, and the protocol will be approved by the Cyprus Bioethics Committee.

Data Acquisition

CROM Measurement

Inertial Sensor System 1: Delsys Sensors

The first inertial sensor system will consist of two surface wireless 3D Delsys Trigno Avanti sensors (Delsys Inc., Natick, MA, USA) embedded with EMG and IMU sensors,

including a 3D accelerometer, a 3D gyroscope, and a 3D magnetometer. The EMG sensor has an input range of 11 mV or 22 mV, a bandwidth of 10–850 Hz, and a resolution of 16 bits. The accelerometer offers a range of ±16 g with a bandwidth of 24 Hz to 473 Hz and a resolution of 16 bits. The gyroscope features a range of ±2000 °/s, a bandwidth of 24 Hz to 360 Hz, and a resolution of 16 bits. The magnetometer has a range of ±4900 µT and a bandwidth of 50 Hz. The sampling rates for the sensors include an EMG sampling rate of 1,259 Hz, as well as sampling rates of 74 Hz for the accelerometer and gyroscope. IMUdata will be recorded using Delsys software, EMGworks Acquisition 4.5.4 (Delsys Inc., Natick, MA, USA), at a sampling rate of 74 Hz. Data will be received as raw IMU data (3D acceleration and 3D gyroscope data on the local coordinate system of the sensor).

Inertial Sensor System 2: Xsens Dot Sensors

The second inertial sensor system will utilise two wireless Xsens DOT wearable sensors (Movella Inc., Enschede, The Netherlands). Each sensor contains a 3D accelerometer, 3D gyroscope, and 3D magnetometer. The gyroscope has a full-scale range of ±2000°/s, a bandwidth of 255 Hz, and a resolution of 16 bits. The accelerometer offers a range of ±16 g, with a low-pass filter cut-off frequency of 324 Hz (262 Hz on the Z-axis) and a 16-bit resolution. Accelerometer and gyroscope sensors sample data internally at a rate of 800 Hz. The magnetometer operates with a full scale of ±8 Gauss, a sampling frequency of 60 Hz, and a resolution of 16 bits. During recordings, data can be saved onboard at rates up to 120 Hz, while real-time streaming is supported at rates up to 60 Hz via Bluetooth 5.0. Orientation data is computed using Xsens' proprietary XKFCore Kalman filter, which fuses data from magnetometer, accelerometer, and gyroscope to estimate drift-free 3D orientation. For this study, the Movella DOT mobile application will be used to control (start/stop), synchronise and collect orientation data as quaternion representations during the measurement. The data will then be exported post-session for further analysis.

Goniometer

A goniometer will be used as the gold standard reference device. Active ROM testing will follow the protocol recommended by Norkin and White (2016). A trained physical therapist experienced in using the UG will conduct the goniometer measurement acquisition.

Data Collection

Delsys sensors and Xsens Dot Sensors will be used to monitor the participant's neck movements throughout the study. Sensor 1 will be placed over the skin at the level of the T1 vertebra using double-sided adhesive tape, while Sensor 2 will be secured within a custom-fitted headband positioned around the participant's head. The headband will then be placed over the external occipital protuberance and the glabella to ensure stable sensor placement. In this configuration, the T1 sensor serves as a reference point representing thoracic posture, while the head-mounted sensor captures actual head motion. By computing the relative orientation between the two sensors, true CROM can be isolated, eliminating trunk or postural contributions. Sensor locations were selected based on previously published protocols with minor modifications (Keidan et al., 2025).

To enable direct comparison and validation, Xsens DOT sensors will be placed adjacent to the Delsys sensors at the same anatomical locations, allowing for simultaneous data collection from both inertial sensor systems under identical conditions.

Experimental Protocol

Part A – Reliability Assessment (Upright and Forward-Leaning Positions)

To establish the consistency and repeatability of both inertial measurement unit (IMU) systems, measurements will be performed under two conditions: lity will be assessed under two conditions: an upright seated position and a forward-leaning position, both of which are relevant to clinical and functional contexts. Performing reliability testing

in multiple postures ensures that the system remains robust across varying biomechanical demands before proceeding to validity evaluation.

In both positions, two wireless Delsys sensors and Xsens Dot Sensors will be used. Sensor 1 will be affixed to the skin overlying the T1 vertebra using double-sided tape, while Sensor 2 will be embedded within a tightly fitted headband positioned over the external occipital protuberance and the glabella. This configuration allows the system to detect true cervical motion by calculating the relative orientation of the head to the thoracic spine, excluding compensatory trunk movement. Before the start of the main trials, participants will also perform a brief calibration sequence consisting of static and slow functional neck movements to assist in aligning the Delsys sensors with the anatomical axes.

Upright Position

In an upright seated posture, participants will perform cervical movements across three planes: sagittal (flexion/extension) in **Trial 1**, frontal (left/right lateral flexion) in **Trial 2**, and transverse (left/right rotation) in **Trial 3**. Each movement will be repeated in a controlled manner for three cycles, with a 5-second hold at the end range and a return to neutral position. This protocol will allow for intra-session reliability analysis. A five-minute break will be included between the initial and repeated trials. During each trial, CROM will be simultaneously measured using both the IMU sensors and a UG, allowing for concurrent assessment of intra-session reliability and criterion validity.

Forward-Leaning Position

In this condition, participants will maintain a stable forward-leaning posture while seated on an SRM ergometer bike (Schoberer Rad-Messtechnik, SRM GmbH, Germany). The handlebars will be positioned low, allowing subjects to lean forward onto their forearms, achieving a nearly horizontal upper-body alignment. This posture has been chosen to reflect occupational and athletic body mechanics.

Neck motion will again be assessed in the three anatomical planes:

- **Trial 4:** Sagittal – Flexion and Extension
- **Trial 5:** Frontal – Left and Right Lateral Flexion
- **Trial 6:** Transverse – Left and Right Rotation

Trials 4–6 correspond to the same movement sequences used in Part A and are not separate data collection sessions. Each movement will be repeated three times, with controlled timing and return to neutral, using the same protocol as in the upright trials. A retest will be conducted after a five-minute rest. Though the sensor placements will remain the same, changes in body orientation may affect the inertial frame, potentially influencing the sensor outputs. Thus, this part of the study ensured that posture-induced variability was accounted for in the system's performance evaluation. Together, the two reliability conditions provide a comprehensive understanding of the IMU system's stability across clinically and functionally relevant postures.

Part B (Validity)

The validation protocol will be conducted with participants sitting upright (vertically) in a chair equipped with back support and armrests. Per the UG angle testing protocol, participants will be instructed to sit up straight, ensuring both feet are firmly and flat on the floor. Additionally, they will be guided to position themselves as far back in the chair as possible while maintaining a neutral sitting position with the thoracic and lumbar spine well supported by the chair back (baseline). Arms will remain rested on the armrests throughout the protocol. The chair used in the study will remain consistent throughout (40 cm x 40 cm x 45 cm) and will be placed in the same location in the room. The electromagnetic field (EMF) will also be tested prior to the study, with minimal EMF detected at the chair and SRM placement sites.

To reduce participant burden and ensure consistency, criterion validity will be assessed using the UG measurements recorded concurrently during the reliability

trials described in Part A. These values will be compared with the corresponding IMU-derived angles. Cervical movements will be performed in the three anatomical planes: sagittal (flexion/extension), frontal (left/right lateral flexion), and transverse (left/right rotation), as already described. Movements will follow the same protocol as described in Part A. The mean of the three repetitions will be used as the representative value for each direction.

Each trial will begin with 20 seconds devoted to calibration, during which the participant will be statically seated to establish baseline. A trained physiotherapist will align the UG during each repetition to obtain concurrent ROM values, ensuring consistent anatomical alignment across repetitions. Goniometric measurement will follow the protocol recommended by Norkin and White (2016) and will be applied during the same trials used for IMU data acquisition. This will ensure a direct one-to-one comparison for the validity analysis. The validity of the UG device requires an upright vertical position to achieve textbook, gold-standard use. Part A (Forward-Leaning Position) of the study will not use UG, so it will not limit movement analysis. This allowed for smoother motion and the addition of another plane of motion. By testing both vertical and horizontal planes, the study provided a more complete understanding of CROM.

Data Analysis

Raw IMU data and orientation data will be collected from the two inertial sensor systems, respectively: Delsys Trigno and Xsens DOT. Data from both systems will be exported as CSV files and processed using MATLAB (version R2024b, MathWorks Inc., Natick, MA, USA) via custom-developed scripts. For the Xsens DOT sensors, orientation will be derived from the provided quaternion data, with an initial calibration step applied to normalize the neutral head posture to zero degrees.

For the Delsys Trigno sensors, raw accelerometer and gyroscope data will be used. A two-step calibration procedure will be applied: (1) the IMU data during the static

postures will be used to estimate anatomical axes based on gravity, and (2) the data from the slow functional neck movements will be used to refine axis estimation using principal component analysis (PCA). These axes will be used to define a transformation matrix between each sensor's local frame and the anatomical frame (sensor to segment calibration). Joint angles between the head and torso will then be estimated using transformed sensor data, based on the relative orientation of anatomical axes derived from gravity and through integration of the gyroscope data for the rotational motions where gravity cannot be captured. This approach avoids direct sensor fusion and enables robust joint angle estimation using carefully designed calibration procedures. This processing pipeline ensures reliable and consistent angle estimation for neck range of motion tasks using both sensor systems.

Statistical Analysis

Part A

A test-retest protocol will be implemented to assess relative reliability. Relative reliability will be evaluated using the intraclass correlation coefficient (ICC), which will be calculated using a two-way random-effects model with absolute agreement for single measurements. The interpretation of correlation strength will follow Cohen's (2013) guidelines, where values between 0.10–0.29 are considered a small effect, 0.30–0.49 a medium effect, and ≥ 0.50 a large effect. In addition to the intraclass correlation coefficient (ICC), the Standard Error of Measurement (SEM) and the Minimal Detectable Change (MDC) will be calculated to evaluate absolute reliability and interpret the clinical relevance of measurement error. The SEM will be calculated using the formula: SEM = SD × √(1 - ICC), where SD will represent the pooled standard deviation of the repeated measurements. SEM will reflect the typical error expected in repeated assessments and will be expressed in the same units as the outcome measure. Lower SEM values will indicate greater measurement precision. To determine the minimum detectable change at a 95% confidence level, the formula MDC95 = 1.96 × √2 × SEM will be used. MDC will represent the minimum amount of change required to be 95% confident that it exceeds measurement error and reflects

a true change. This will be particularly useful for clinical interpretation when monitoring progress over time.

Part B

To assess the measurement validity, data from the two IMU systems will be compared to the gold standard non-invasive UG. Analyses will be conducted using SPSS v27 and Python. All outcome measures will be tested for normality and homogeneity of variance. Validity will be assessed using the Pearson product-moment correlation coefficient between the UG and each IMU. Additionally, modified Bland-Altman analyses, incorporating random effects models to account for repeated measures, will be employed to evaluate the agreement among the three measurement methods, thereby enhancing the precision of within-subject variance estimation.

Ethical and Bioethical Considerations

The sensors are non-invasive and pose no risk to the user. The only data to be stored will be the user's CROM measurements. The measurements will be stored anonymously; there are no concerns regarding personal data protection (GDPR). No personal user data will be stored.

Study Timeline

The data collection is expected to commence in July 2025 and be completed by September 2026. Data analysis and interpretation will follow, with the final report prepared by December 2026.

Consent and Right to Withdraw

Participation in this study is entirely voluntary. Individuals who agree to take part will be asked to carefully read the participant information sheet and provide written informed consent before any testing procedures begin. Participation involves non-invasive measurement procedures using wearable sensors, conducted under the supervision of trained personnel. Participants may withdraw from the study at any

time, without providing a reason and without facing any negative consequences. They may also request the removal of their data at any stage. To do so, they should contact the principal investigator, Dr. George Pamboris (G.Pamboris@euc.ac.cy), who will ensure that all personal data is immediately and permanently deleted without question.

If participants have any concerns or wish to file a complaint, they may contact Professor Marios Vryonides, Vice Rector for Research and External Affairs at European University Cyprus. Full contact details for this independent contact person will be provided prior to participation, allowing direct communication outside the research team.

Potential Benefits and Risks for Participants

Although participants may not receive direct personal benefits from their involvement, their contribution to this research will play a valuable role in advancing scientific understanding of CROM) assessment. Specifically, the findings may inform improvements in diagnostic accuracy and rehabilitation strategies using wearable inertial measurement systems. These insights could support the development of more precise and ecologically valid tools for evaluating neck function and postural control, ultimately benefiting future clinical populations with cervical dysfunction or balance impairments.

The study involves minimal risk. All procedures are non-invasive and limited to standard head and neck movements that participants perform in daily life. Minor discomfort, fatigue, or muscle stiffness may occur due to repeated or sustained postures, especially during the forward-leaning condition. To mitigate this, rest periods will be provided between trials, and participants will be allowed to stop the assessment at any point if they feel uncomfortable.

No electrical stimulation or invasive techniques will be used. Sensors will be affixed using hypoallergenic, double-sided adhesive tape. While skin irritation is not

anticipated, individuals with known skin sensitivities or allergies to adhesives will be excluded from participation. The protocol has been carefully designed to prioritise participant safety, with all procedures carried out under the supervision of trained professionals.

Data Storage

Electronic data will be stored on a password-protected computer. All personal data will be kept in a format that does not allow participant identification. Data will be anonymised using unique codes and stored electronically by Dr. Pamboris, who will be the only person with access to the file. Two years after the completion of the study, all data will be permanently deleted. After the study concludes, only the scientific lead will have access to the coded data. The data will be securely stored on Dr. Pamboris's personal storage device at European University Cyprus, in a locked digital folder. The university adheres to all prescribed electronic security measures to prevent any data theft from employee computers. In addition, all university premises are protected by a 24-hour private security presence.

Study Results

The results of the research project will be disseminated via a peer-reviewed scientific publication and presented at international scientific conferences.

Complaints Procedure

Participation in the study is voluntary, and participants may withdraw at any time without facing any negative consequences. Prior to participation, all participants will be informed of the independent contact person to whom they can submit any complaints or concerns. This person is the Vice Rector for Research and External Affairs of the European University Cyprus, Professor Marios Vryonides. Full contact details for the independent contact person will be provided before the study begins, allowing participants to communicate directly with them without involving the research team.

European University Cyprus

6 Diogenes Street, 2404 Engomi, Nicosia
P.O.Box 22006, 1516 Nicosia, Cyprus
T: 22713000, F: 22713172, E: info@euc.ac.cy
www.euc.ac.cy

Dr George M. Pamboris

George Pamboris, PhD | Assistant Professor
MSc Sports Physiotherapy Coordinator
Department of Health Sciences
[a] 6, Diogenes Str. Engomi, 2404 P.O.Box 22006,
1516, Nicosia, Cyprus
[t] +357 22713151 [f] +357 22559405
[e] G.Pamboris@euc.ac.cy [w] www.euc.ac.cy

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