Description of the Study
To test the reliability of an inertial measurement unit (IMU) during sport specific movements. The IMU is a wearable device that measures human movement, i.e. speed, acceleration, and leg orientation (angles). The aim is to determine if accelerations measured with the IMU are reliable over multiple days when performing similar tasks, i.e. sprinting, side-step, etc. This study will be conducted outdoors and not necessarily at a Partners institution.

The IMU is a non-significant risk device. This is not a clinical trial. All participants are healthy active adults. We are not testing or validating the device for the Vendor. The device is commercially available. The Vendor is not sponsoring this study.

The IMU Sensor
The official name is Vicon Blue Trident Model V2. The Vendor of the IMU is named: Vicon – IMeasureU. All Safety & Regulatory Information and manuals can be found at the link provided at the end of the document. The device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15(c) of the FCC CFR47 rules. The Bluetooth Declaration ID is DO43233.

![Figure 1. Blue Trident IMU](image)

The sensor dimensions are 42 x 27 x 11mm and weighs 9.5g (Figure 1). The device has an IP68 rating. The device consists of 3 inertial sensors including an accelerometer (measures acceleration), a gyroscope (measures angular velocity) and a magnetometer (measures magnetic fields). The device also contains onboard memory and a battery. The vendor does not explicitly state the size and voltage of the battery. It is a rechargeable lithium-ion. The device can transmit data wirelessly through Bluetooth and downloaded through USB. The device can be worn anywhere on the body. Most often it is attached to the shin using straps or athletic tape (Figure 2). In this case two (2) IMUs will be used. One on the left leg and one the right leg.

![Figure 2. Blue Trident IMU attached to lower leg.](image)
Vendor Contact Information
Telephone: +1.303.381.4944
Email: support@vicon.com

Planned Intended Use
The IMU is a limb worn sensor that is intended to collect, store, and transmit inertial data to a qualified system provided by the Vendor for use by both researchers and clinicians. The inertial data measured includes speed, acceleration, and leg orientation (angles).

Planned Indications for Use
The IMU is indicated for multiple use, i.e. the same IMUs will be used by all subjects. The IMU is intended to measure data over both short and long bouts. Short bouts would include clinical exams, i.e. hops and jumps, while long bouts would include fatigue running protocols or athletics events (full sporting event, i.e. game or practice).

Product Packaging and Shipment
The IMU has an IP68 rating and therefore can be washed and used by multiple subjects. Devices will be labeled for investigational use only but are all labeled with a unique serial number by the Vendor. Products will be either shipped or hand-carried by the investigator to the investigational site.

Data Flow
The IMU Blue Tridents will used in this protocol as part of the “IMU Step” workflow for this study. The Vendor provides multiple avenues for data collection with this device, but the IMU Step workflow will be described below. There are 3 steps in the data flow: A Mobile App, a Desktop Application, and a Cloud Service (Figure 3).

Figure 3. Data flow. The IMU Step Mobile App triggers start and stop of data collection to the IMU. The data is then downloaded via USB to a computer using IMU Step Desktop Application. Data is then uploaded using the IMU Step Desktop Application to the IMU Step Cloud Service.

IMU Step Desktop Application
The Vendor provides a Desktop Application in order to facilitate the downloading of data from the IMU to a computer and uploading of this data to the IMU Step Cloud Service. The IMU Step Desktop Application will be installed on a Windows OS 10 device. The IMU Step Desktop Application requires a
username and password in order to open. These are unique for each user and provided by the Vendor. The IMU Step Desktop Application facilitates:

- IMU firmware upgrades
- IMU data download (only through USB)
- IMU data upload to the IMU Step Cloud Service (will primarily be through Wi-Fi)
- Erasing data from the IMU

**Windows 10 Device**

A Windows 10 Laptop will be used for this study. The device is a DELL G3 15 laptop. This device is a non-standard Partners computer. A username and password are needed in order to log into the device. Procedures will be followed so this device meets the requirements outlined by Partners Information System including Network Access Control (NAC) with Secureconnector, Anti-virus with Updated Definitions, Patching/Software Updates, Endpoint Protection with CrowdStrike, and Data Backup workflow. Note: no IMU data or PHI is stored on this device. It only facilitates download and upload to the IMU Step Cloud Service. Upload will happen through Wi-Fi. Upload may happen both on and off-site, depending on the performance site location and where the study staff choose to download/upload the IMU data. The laptop is housed at the Spaulding National Running Center Research Laboratory at the Spaulding Rehabilitation Hospital in Cambridge.

**IMU Step Cloud Service**

The Vendor provides a cloud-based service called IMU Step. This service is required to process, store, and visualize data from a research database specific to each protocol the devices are used in. The cloud service is hosted by the Vendor. The cloud service can be accessed through any web browser. The cloud service requires a unique username and password that is provided only to the investigator by the Vendor. Only the investigator specific to the protocol has access to this cloud service and database. No PHI is collected by the cloud service. The investigator creates “athletes” by using non-identifiable IDs.

**IMU Step Cloud Database Server**

It is unknown to the study staff how the database backend is structure. Please reach out to the Vendor using support@vicon.com

**IMU Step Mobile App**

The IMU Step Mobile App is an iOS-based tablet application used to manage subject association with each IMU, start and stop data collection, and display system performance data. The App will be installed on an Apple iPad (described in 2.6) iOS Device. In order to use the IMU Step Cloud Service, the IMU Step Mobile App must be used to collect the data. No inertial data is transmitted to the App or stored on the iPad. Only the study staff handles the iPad and the use of the IMU Step Mobile App. The App is able to connect to 12 IMUs at once. The App integrates with and has access to other Apps (i.e., iCloud, Photos, OneDrive, Dropbox, etc.). The App does not collect any background data or perform any synchronization. The study staff is unsure of the encryption protocol. The App uses Bluetooth to connect with the IMUs. The App does not need to be connected to the internet to perform its function. The app does communicate with the Vendor database in order to sync the Subject ID database, i.e. if a subject was added to the database using the IMU Step Desktop Application then the Subject ID will now appear within the App.
iOS Tablet
The iOS tablet is a commercial-off-the-shelf (COTS) Apple iPad required to run the user interface (UI) for the study (IMU Step Mobile App, described in 2.4). It will be managed by study staff for the duration of the study. The model is an iPad Mini (5th Generation MUQW2LL/A) running iOS 12.3.1. The device has been purchased through Partners Healthcare and has therefore gone through Apple Professional Services (APS) for asset tagging. This includes installation of MobileIron through the Partners EMM / MobileIron team. The iPad requires a 6-digit passcode to unlock. The pin was set-up by the research manager and distributed to study staff when necessary. The iPad does not require internet access in order to perform its purpose. All non-essential iOS apps have been removed from the iPad. The research manager does have the ability to install new Apps on the device using a Spaulding National Running Center Research Laboratory Apple ID account when required. The device is configured to disallow sync services and background uploads, except for the App Store to keep the IMU Step Mobile App up-to-date. Voice assistant is disabled. GPS is enabled. There are no browsing restrictions. OS updates are configured to be applied manually. No other data is cached to the knowledge of the study staff. The lockout time is set to 2 minutes. When Bluetooth is enabled during data collection, the Wi-Fi is disabled. When the Bluetooth connection is no longer required Wi-Fi is then re-enabled when required. The iPad will be stored in a travel case at the Spaulding National Running Center Research Laboratory at the Spaulding Rehabilitation Hospital in Cambridge when not in use. The travel case will be used to transport the iPad to and from the performance sites (Figure 4).

![Travel case prototype.](image)

Study Procedures
Number of IMUs
Two (2) IMUs are required for this study and will be used by all subjects.

Number of Subjects
Subject numbers will be a maximum of 20.
Study Duration
The study will last about 6 months. Each subject will be collected a total of 3 sessions, 7-10 days apart. Each session, from start to finish, should last no more than 1 hour.

IMU Placement
The study staff will place IMUs on the lower portion of the shin bone for both the left and right legs. The IMU will be secured using under wrap and athletic tape by the study staff.

The serial number of the IMU and associated subject ID will be recorded in the subject log. The identification number of the IMU associated to each leg (left or right) will be recorded in the subject log which will be a REDCap instrument.

IMU Storage
The IMUs will be stored in the travel case at the Spaulding National Running Center Research Laboratory at the Spaulding Rehabilitation Hospital in Cambridge when not in use. IMUs will be kept in the travel case during travel to and from the performance sites.

IMU Pairing
The IMUs are first placed on the subject.

The study staff will sign into the IMU Step Mobile App on the iOS device using a Vendor provided username and password. The App is not accessible or useable without logging into the App.

The study staff will then create a new subject and enter their study-assigned unique Subject ID.

Study staff will then assign and pair the IMUs to the IMU Step Mobile App using the iOS device. The App ‘wakes’ the IMU. The subject does not interact with the App or iPad or IMU (other than having it attached).

The study staff will start the collection using the App. The study staff will stop the collection using the App. Stopping the collection unpairs the IMUs.

Assigning IMU to Existing Subject (Follow up)
The previous steps are followed during a follow up data collection, except for subject creation. During follow up, the study staff will select the appropriate subject ID from the subject list in the App, and then pair the IMUs followed by data collection.

Performance Metrics
Data stored in the IMU Step Cloud Database will be processed by an automated algorithm created by Vendor to determine the leg accelerations, number of steps taken, and intensity of accelerations for each step.

These metrics will then be downloaded from the Cloud Database by the study staff in the form of a comma separated file onto a Partners RFA in order to run statistical analyses.

Data Handling and Record Keeping
No clinical information is collected.
PHI including name and birthdate will be collected and stored using REDCap. The subject log will also be incorporated into REDCap. No PHI will be contained in the Cloud Database, on the App, on the IMU, or the RFA. Data entry into REDCap will occur on-site using standard Partners computers or REDCap mobile app.

**Data Contained in Cloud**
Data downloaded from the Cloud Database will be housed within a secure server and accessible only to the study personnel and investigators, in the form of a Partners RFA. Access to this RFA is distributed by the research lab manager. The processed data remains in the cloud until the Vendor is notified to remove it at the completion of the study.

**Data Contained on IMU**
Raw inertial data is logged onboard of the IMU during data collection. The data can only be accessed using the IMU Step Desktop Software. The data is downloaded from the IMU and pushed to the Cloud using the IMU Step Desktop Software. The IMU Step Desktop Software does allow for the raw data to be downloaded from the IMU to the RFA but will not be used in this study. In the event the raw data is required, the files are in comma separated format and are automatically named using the serial number from the IMU it was collected with and the timestamp of the collection. No PHI is contained in the file name of the raw data file.

Once the data is downloaded and subsequently uploaded to the Cloud using the IMU Step Desktop Software, the data is erased off the IMU using the IMU Step Desktop Software.

**Data Contained in App**
The App does not store any data other than the Subject ID and the time stamps of previously collected trials. These timestamp logs are erased manually from the device.

**Links to Regulatory Documentations and Manuals**
https://docs.vicon.com/display/IMU/IMU+documentation