



IMPACT MONITOR MOUTHGUARD

| Gen 1.3 Instructions for Use |

Revision 1.3.1

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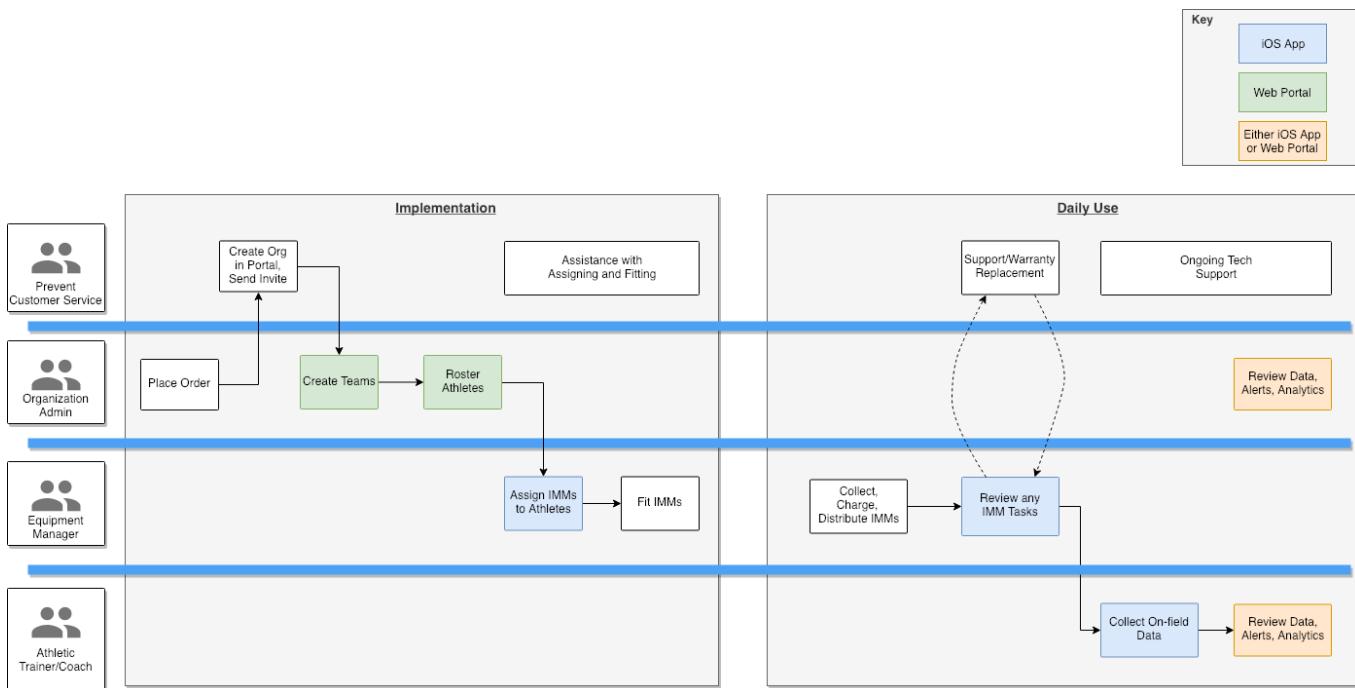
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PRODUCT DESCRIPTION

The Prevent Biometrics head impact monitor system comprises an impact monitor mouthguard (IMM), a tablet or smartphone with installed app that communicates with the IMM(s) to monitor head impacts in real time, and individual and team charging cases that wirelessly charge the IMM. The impact monitor measures impact force and location and reports them via the app interface for use by team personnel. The app allows team personnel to establish an impact alert trigger for players and will provide an alert when an impact above the alert trigger has been exceeded.

SETUP AND USE OPERATIONS





WARNINGS & CAUTIONS

- The head impact monitor is not a replacement, substitute or adjunct of any existing methods for identifying athletes for evaluation due to head impacts. The head impact monitor does not indicate, diagnose or assist in diagnosis of a concussion. Impact data is used to indicate to staff that an impact event has occurred and reliably measure it.
- The head impact monitor does not provide any protection against head impacts.
- Before every use, inspect the product to ensure no damage to the seal of the circuit board is evident. Discontinue use if damage is seen.
- Before every use, inspect the product to ensure no damage to the battery or seal around the battery is evident. Discontinue use if damage is seen.
- Ensure that the impact monitor mouthguard is not subject to temperatures higher than 100 °C (212 °F). Ensure that the impact monitor mouthguard is not subject to 60 - 100 °C (140 - 212 °F) for more than 1 minute.
- Use only the wireless charger provided with the product for charging.
- Avoid cross contamination of impact monitor mouthguards.
- Clean the impact monitor mouthguard by either rinsing in cold water or using a toothbrush to remove debris while rinsing. Do not use toothpaste or detergents, and do not place in dishwasher or under hot water.
- Do not leave the impact monitor mouthguard in a hot vehicle in direct sunlight.
- Do not place the impact monitor mouthguard in microwave.
- Do not operate charger outdoors.

Per FCC 15.19(a)(3) and (a)(4) This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Per FCC 15.21, users should not change or modify to the product.

FCC ID 2AUV5IMM1-3



IMM TECHNICAL SPECIFICATIONS

Performance	
Impact Detection Accuracy	± 5%
False Positive Filtering	99%
Range of Impact Detection	± 200 g
Sample Rate	3200 Hz
BLE Range	60 ft (18.28 m)
Impact Data Storage	450 Impacts
Mechanical	
Outer Material	Food or Medical Grade Polyurethane and EVA
Size (L, W, H) and Weight	6.5" x 5.0" x 2.0", 21 g
Environmental	
Temperature (Operation)	-20 – 60 °C / -4 – 140 °F (use) 0 – 45 °C / 32 – 113 °F (charging)
Altitude (Max Operation)	5000 meters (16,404 ft)
Temperature (Shipping & Storage)	-20 – 45° C
Power	
Charging Method	Wireless
Battery Type	Polymer Lithium-ion
Battery Life (In Use, Standby)	7 h
Interface	
Impact event data transmission	Bluetooth Connection to iOS
Indicators	Red, Yellow, Green LEDs

Product Patent Protections – Mouthguard and/or Associated Mobile App

- U.S. Patent 9,149,227 – DETECTION AND CHARACTERIZATION OF HEAD IMPACTS
- U.S. Patent 9,289,176 – CLASSIFICATION OF IMPACTS FROM SENSOR DATA
- AU Patent 2011278996 – DETECTION AND CHARACTERIZATION OF HEAD IMPACTS
- AU Patent 2011278997 – CLASSIFICATION OF IMPACTS FROM SENSOR DATA
- CA Patent 2,805,252 – DETECTION AND CHARACTERIZATION OF HEAD IMPACTS
- CA Patent 2,805,250 – CLASSIFICATION OF IMPACTS FROM SENSOR DATA
- EP Patent 2,593,010 – DETECTION AND CHARACTERIZATION OF HEAD IMPACTS (Validated in GB, DE, FR, IT, and ES)
- EP Patent 2,593,015 – CLASSIFICATION OF IMPACTS FROM SENSOR DATA (Validated in GB, DE, FR, IT, and ES)

Other Patents Pending.



INDIVIDUAL CHARGER CASE TECHNICAL SPECIFICATIONS

Power supply	
Voltage input (DC Volts)	4.5-5.5
Maximum current draw (Amps)	0.5
Mechanical	
Material	Polypropylene
Size (L, W, H) and Weight	3.5" x 3.75" x 1.0", 60 g
Environmental	
Humidity (Operation)	65 ± 20% RH
Temperature (Operation)	0 – 45 °C / 32 – 113 °F
Altitude (Operation)	5000 meters (16,404 ft)
Ultraviolet Sanitization	
UV wavelength (nm)	280
Average UV power (mW)	4

TEAM CHARGER CASE TECHNICAL SPECIFICATIONS

Power supply	
Voltage input (AC Volts)	100-240
Maximum current draw (Amps)	1.52
Mechanical	
Material	Polypropylene
Size (L, W, H) and Weight	3.5" x 3.75" x 1.0", 60 g
Environmental	
Humidity (Operation)	65 ± 20% RH
Temperature (Operation)	0 – 45 °C / 32 – 113 °F
Altitude (Operation)	5000 meters (16,404 ft)
USB port	
USB voltage (V)	5
Maximum USB current output (A)	2

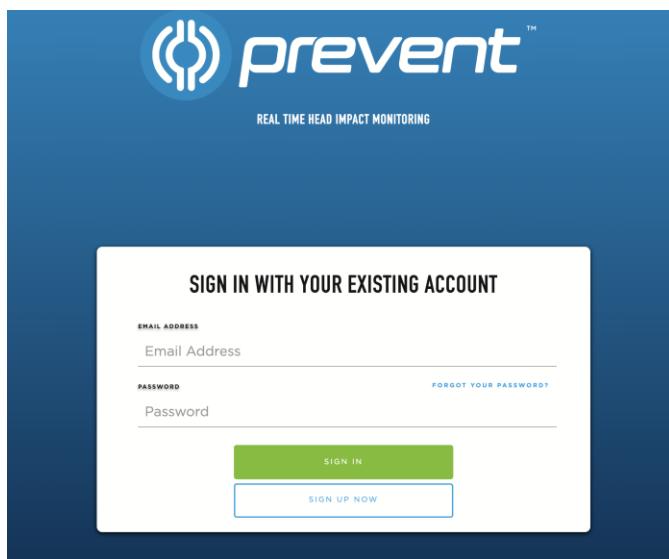
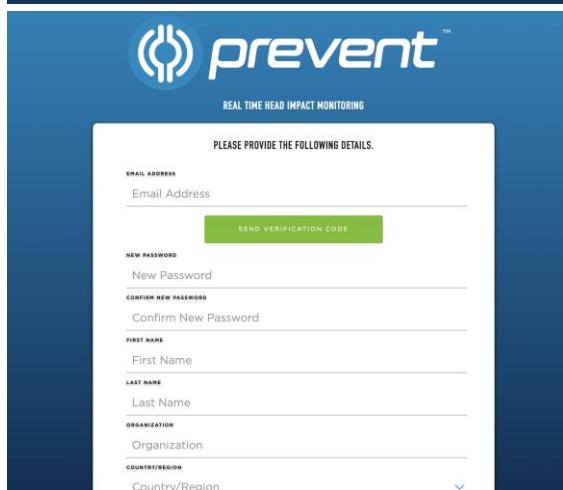


PORTAL SETUP

The first step in the process of setting up your impact monitor system is to gain access to the portal. The portal is where most administrative functions are performed, including populating your team roster so that impact monitors can be assigned to players. At the time of purchase, Prevent staff will invite you to create an account to access the portal.

LOGGING IN

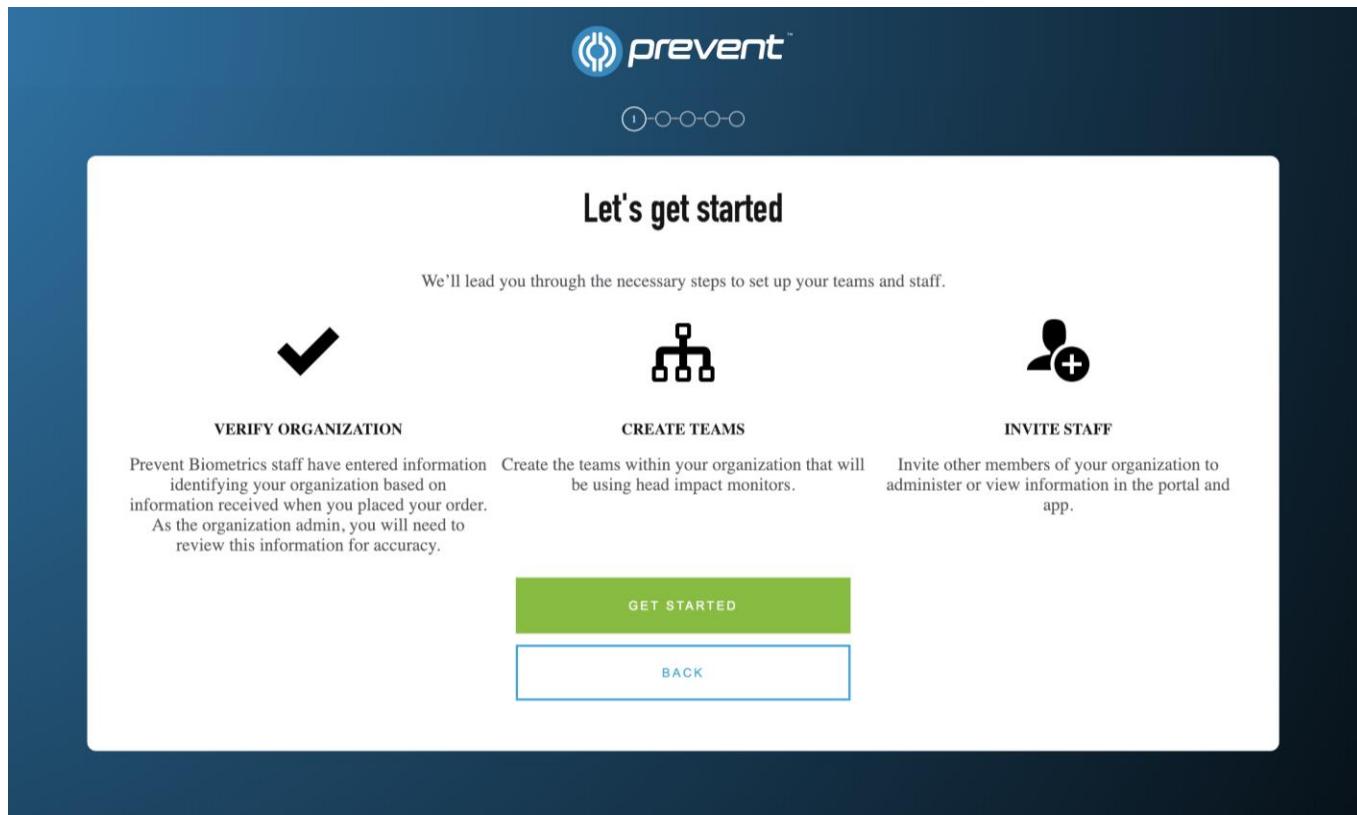
Once Prevent staff have set up your organization in the portal, you will receive an email inviting you to create an account.

A screenshot of the Prevent biometrics sign-in page. The page has a dark blue header with the 'prevent' logo and 'REAL TIME HEAD IMPACT MONITORING' text. Below this is a white sign-in box with the heading 'SIGN IN WITH YOUR EXISTING ACCOUNT'. It contains fields for 'EMAIL ADDRESS' (Email Address) and 'PASSWORD' (Password), both with placeholder text. To the right of the password field is a 'FORGOT YOUR PASSWORD?' link. Below the fields are two buttons: a green 'SIGN IN' button and a white 'SIGN UP NOW' button.A screenshot of the Prevent biometrics sign-up page. The page has a dark blue header with the 'prevent' logo and 'REAL TIME HEAD IMPACT MONITORING' text. Below this is a white sign-up box with the heading 'PLEASE PROVIDE THE FOLLOWING DETAILS.' It contains several input fields: 'EMAIL ADDRESS' (Email Address), 'NEW PASSWORD' (New Password), 'CONFIRM NEW PASSWORD' (Confirm New Password), 'FIRST NAME' (First Name), 'LAST NAME' (Last Name), 'ORGANIZATION' (Organization), and 'COUNTRY/REGION' (Country/Region). A dropdown arrow is visible next to the 'Country/Region' field. To the right of the 'EMAIL ADDRESS' field is a green 'SEND VERIFICATION CODE' button.



ORGANIZATION SETUP

On first entry to the portal, a setup wizard will guide you through your initial setup of your organization, first teams, and team staff.



ROSTERING ATHLETES



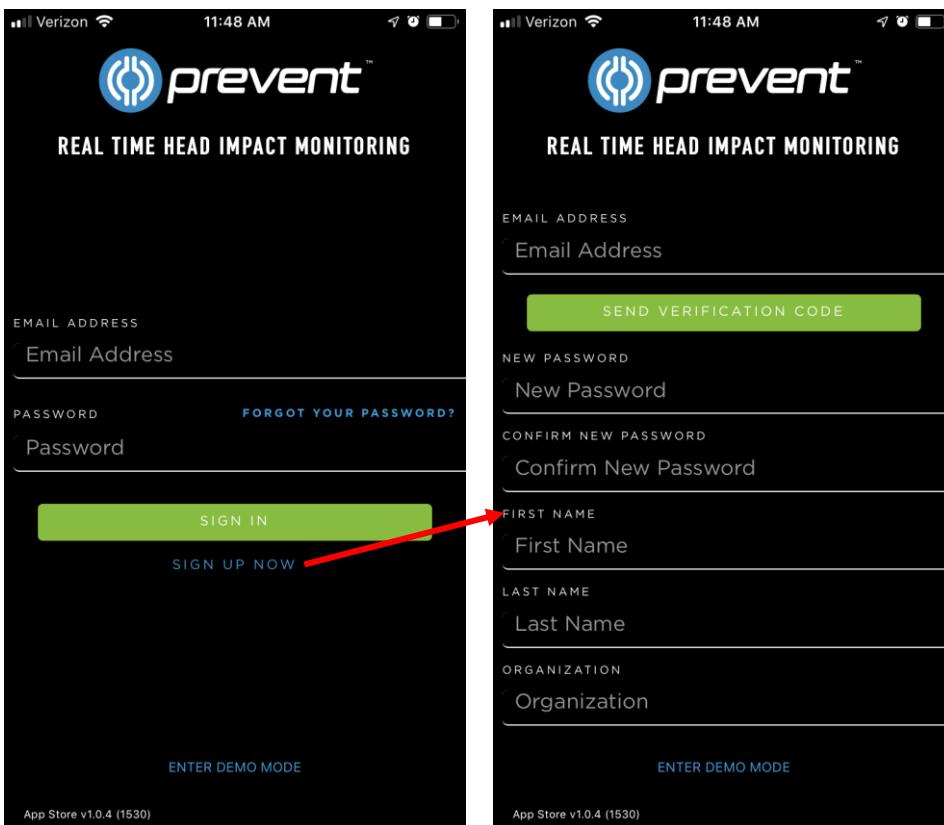
TEAM APP INITIAL SETUP

The team app is the “Dashboard” for the impact monitor system. Most operations with the impact monitor are done with the team app, including viewing data and alerts, updating firmware, and checking the health of the impact monitors. This section will walk you through initial setup of the team app.

LOGGING IN

During organization setup in the portal, you will see a link to download the app. The can also be downloaded from the Apple App Store by searching for “Prevent”.

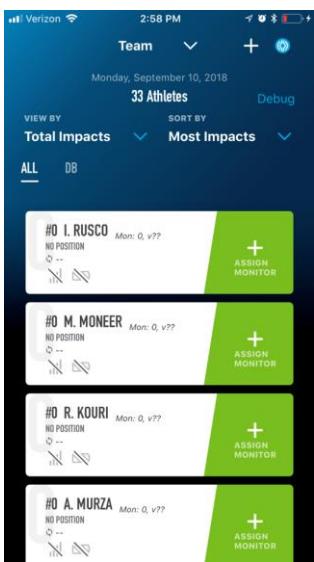
Upon opening the Team App, you will be presented with the login page. If you have not already set up an account in the portal, click “Sign Up Now” to create an account.





ASSIGNING IMPACT MONITOR MOUTHGUARDS

First, select the team you would like to view from the drop-down menu at the top of the app. Each monitor has a unique serial number that identifies data sent to the team app. Before beginning use, each monitor must be assigned to a player.



Begin by selecting the team of interest within the team app. Click the [Assign Monitor](#) button attached to the player you would like to assign a monitor to.



Center the serial number barcode for the device in the frame, and the team app will capture the device's identity and automatically assign it.

At this point, the monitor is paired with a player. Take care that this monitor is now identified to be owned by the correct player. This can be done by writing the player's name on the packaging, or by placing it in a charging case that has been labeled.

IMPACT MONITOR MOUTHGUARD INITIAL FIT



Boil water - Boil enough water to a boil to completely cover the IMM. Ensure the water is at a rolling boil.



Heat IMM - Using a slotted spoon or tongs, suspend in the water for exactly 50 seconds. Have a timer ready and do not exceed 50 seconds.



Remove IMM - Remove the IMM from the water. Shake any remaining water off, and immediately proceed to the next step. Any delay will negatively affect fit.



Center & Fit - Carefully center the IMM in your mouth and firmly press the IMM onto the upper teeth. Having a mirror available to assist in centering the mouthguard before fitting may be helpful.



Bite – Bring the lower jaw up to a comfortable position and bite down firmly, ensuring that you bite all the way through the soft dentition encasement material (blue), up to the harder dental tray (grey).



Press & Suck – While biting down, suck in continually and press (with 2-4 fingers) on the front of the IMM for 30 seconds, pushing the front teeth up to the front of the IMM.



Wait – While continuing to bite down, leave the IMM in your mouth for an additional 30 seconds.

Cool – If available, run the IMM under cool water for 30 seconds. Otherwise, allow the IMM to air cool for at least 2 minutes.

IMPACT MONITOR – CHARGING

Charging Case

If the blue IMM tooth-molding material is sticking out past the end of the IMM and is interfering with the ability to push the IMM all the way back in the alignment slot, it can be trimmed with scissors. Caution: Only trim the blue IMM tooth-molding material. Do not trim the clear or gray material.



Place the IMM in the charging case and securely close the lid. Ensure the IMM is pushed all the way down in the charging case, as shown in the photo.



CHARGING VIA USB CABLE

Plug the charging case into a USB micro cable plugged into a USB power source.



INDICATOR LIGHTS

- NOT CHARGING, CHECK IMM PLACEMENT
- CHARGING
- 2 MIN UV SANITIZATION CYCLE

The IMM should emerge from sleep mode within about 15 minutes of charging and should be fully charged in 70 minutes.



CHARGING WITH TEAM CASE

Plug the charging case into any slot in the team case. Ensure the team case is plugged into mains power.



INDICATOR LIGHTS

- NOT CHARGING, CHECK IMM PLACEMENT
- CHARGING
- 2 MIN UV SANITIZATION CYCLE

TEAM CASE AUXILIARY CHARGING PORT

The team case includes an auxiliary USB charging port at the bottom of the case. The port is rated for 1A charging and can be used to charge a smartphone or tablet.



IMM OPERATION

The impact monitor is always on and active whenever it is charged. There is no preparation required after removing it from the charger. Simply wear it in your mouth like a normal mouthguard, and monitor measurements with the Prevent Team App.

SYNCING BEFORE AND AFTER USE

For best data results, the IMMs should be synced often with an iOS device. This is done by simply ensuring that the app is open on an iOS in proximity to the IMMs. It is especially important that all devices are synced before use as close to the beginning of the use event as possible. This allows the IMMs to have the correct time of day, so that the app can most accurately display the correct time of the impact event.

It is also important to ensure that the app is synced with the IMMs after use. Again, this is achieved by opening the app on an iOS device in proximity to the IMMs.

FUNCTIONALITY CHECK

Before use, the IMMs should be checked for functionality. About 15 seconds after being removed from the charger, the IMM should blink green for 15 seconds. Please note, this will only occur when the IMM is taken off active charging, so the charger case must be lit green when removed (not white). If this does not occur, ensure that the IMMs have been charged at least 70 mins.

While viewing the team page in the team app, ensure that all monitors are displaying that they are actively connected to the app via BLE. This ensures that the monitors are charged, active, and functioning. If these checks are successful, the IMMs are ready for use. If not, please see the troubleshooting section.

CONDITIONS FOR IMPACT DETECTION

The Prevent IMM automatically detects whether an impact is a false positive, meaning that it is an impact measured by the mouthguard that does not exhibit the characteristics of a head impact.



TEAM APP OPERATIONS

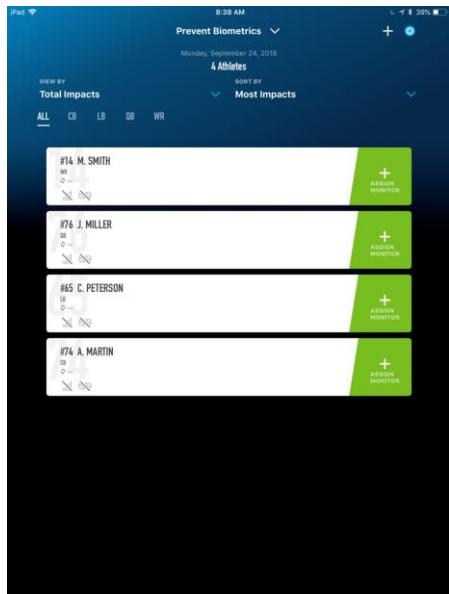
This section will lead you through the general operations of the team app once the IMMs are set up and ready to use.

IMM FIRMWARE UPDATE

Initially and periodically, your IMM(s) will need updated firmware. This will be evident by the appearance of an "Update" button on the player's pane in the team app when connected to the IMM. Firmware updates are best done when on the charging system. Ensure that you have an internet connection on the app device, and simply press the "Update" button and confirm. The IMM will blink red until the firmware update is complete.

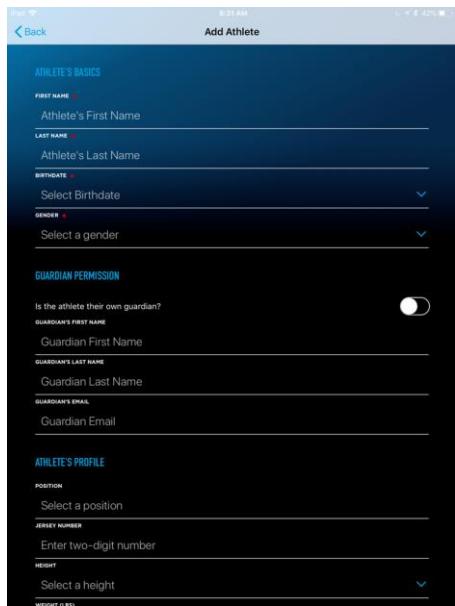
TEAM ROSTER PAGE

Tapping the **TEAM** icon at the bottom of the screen will bring you to this page:

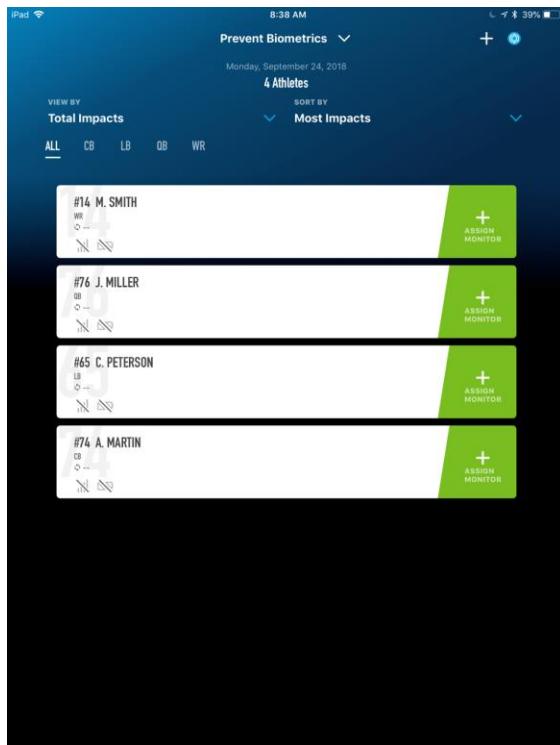




To add an athlete, tap the "+" button in the top right. You will be presented with the add athlete page. Required fields are indicated in red:



To assign an Impact Monitor to the athlete, tap the "+ ASSIGN MONITOR" button:



This page will allow you to barcode scan the serial number barcode associated with a IMM in order to assign it to a player:

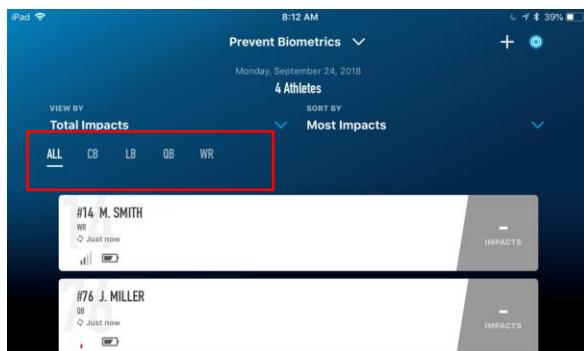


If the barcode cannot be scanned, click the "Having Trouble?" button at the bottom of the screen to type the serial number.

Once athletes are assigned, the team data view can be adjusted in the following ways:

Filter by Position

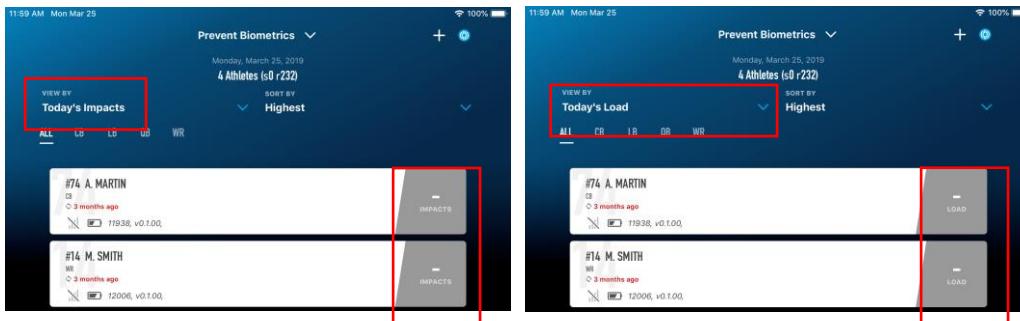
The team list can be filtered by position, if athletes have been input with a position assigned. Click a position in the position bar above the player list. Tap "ALL" to remove the filter.





View Impact Quantity or Impact Load

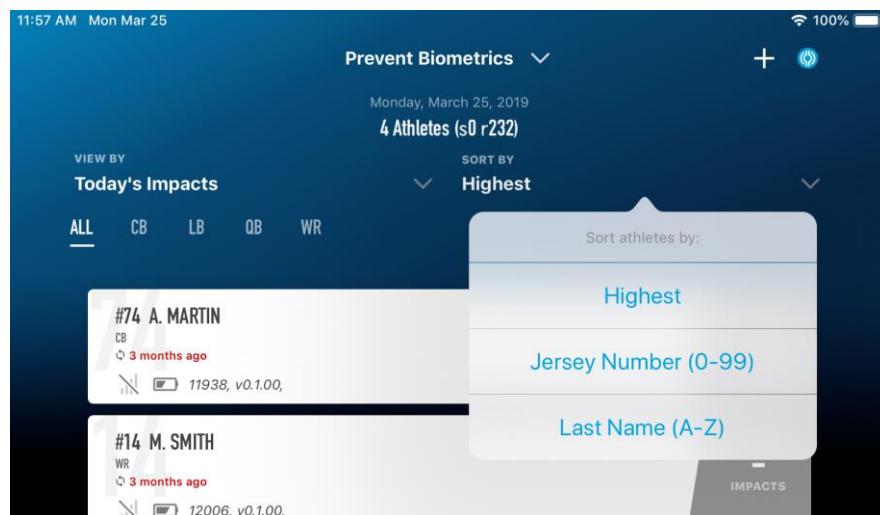
The quantity indicator next to each player can list the total quantity of impacts for the day, or the Impact Load for the day. This can be changed in the "VIEW BY" drop down.



Impact Load is a composite of the quantity and magnitude of impacts for the day.

Sort by

Players can be sorted using the "SORT BY" dropdown by the following criteria:





ATHLETE DETAIL

Tap on an athlete's bar to open the Athlete Detail page. When an athlete's monitor records an impact it will appear in this screen:

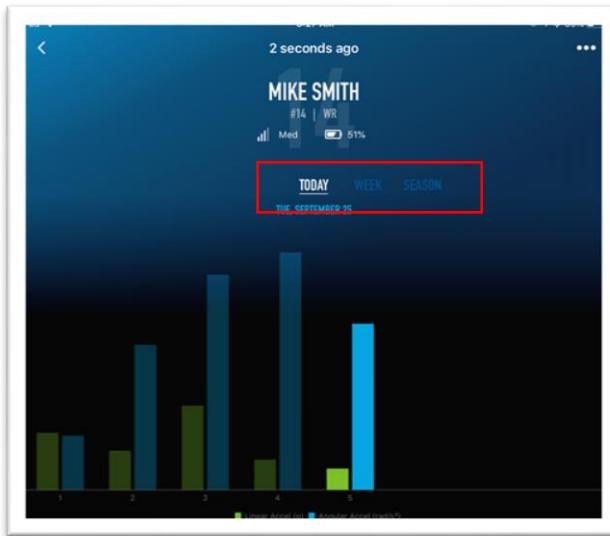


If the athlete experiences an impact over the alert trigger it will appear in red:

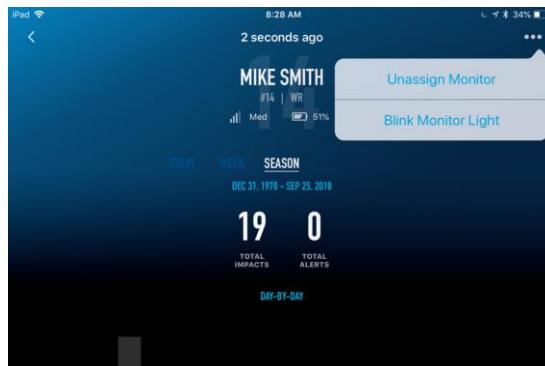




Impacts can be viewed within the context of Today, this Week, and this Season. To view impacts in the past, select the Season view and select a date in the past.



If an IMM must be replaced, click the 3 dots in the player page and select "Unassign Monitor":

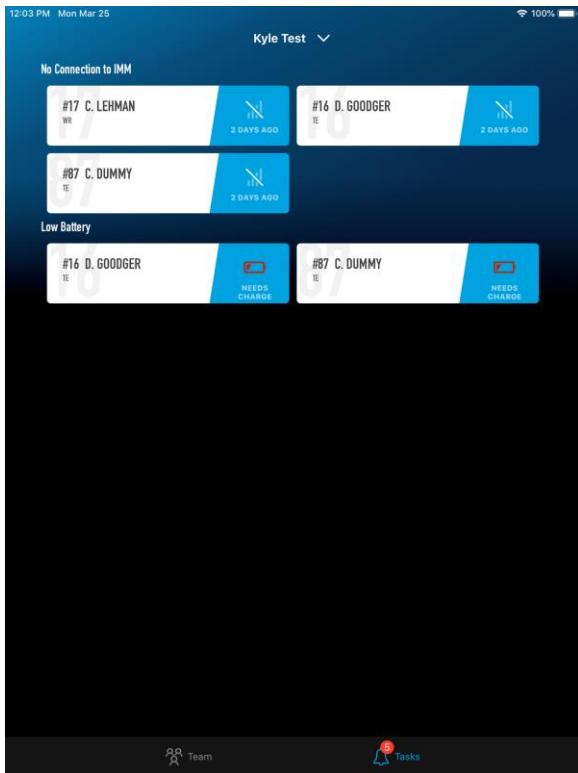


Once unassigned, the player will drop to the bottom of the team list and will now have the option to assign a new IMM.



TASKS PAGE

The Tasks page is the main interface for ensuring the IMMs are working correctly and are communicating with the iOS app. Any issues will be reported as tiles attributed to the athlete's monitor that exhibiting an issue:



Tasks are presented in the following categories:

- No Connection to IMM: The IMM has not communicated with iOS for more than 15 minutes.
- Low Battery: The IMM is in a low battery state and should be charged as soon as possible.
- Firmware Update: A firmware update is available for the IMM.
- Impact Alert: Evaluate athlete, high magnitude impact collected.



PORTAL OPERATIONS

This section will lead you through general operations in the team portal, once initial setup is complete.

REPORTING SCREEN

A screenshot of the prevent biometrics reporting interface. The top navigation bar shows the prevent logo, a user icon, and the text 'CURRENT ROSTER'. Below this, a sub-header indicates '2018 Fall Pilot Testing'. On the left, a sidebar lists 'Teams' and 'CURRENT ROSTER'. The main content area is divided into three sections: 'MOST IMPACTS', 'HIGHEST LOAD', and 'IMPACT SUMMARY'. The 'MOST IMPACTS' section lists players with the highest impact counts. The 'HIGHEST LOAD' section lists players with the highest average load. The 'IMPACT SUMMARY' section is a histogram showing the distribution of impact counts. The top right of the screen displays summary statistics: '7,204' impacts, '0.11' average load, and '0' alerts.



SYSTEM TROUBLESHOOTING

Symptom	Cause	Solution
Red light on charger case	Poor IMM alignment in case or missing IMM.	Check IMM alignment in case
"No Connection to IMM" Task	IMM not charging or broken.	Ensure proper charging. If not remedied in 20 minutes, please contact Prevent for additional troubleshooting steps or a replacement at support@preventbiometrics.com
"Low Battery" Task	IMM is running low on battery	Return to the charger case as soon as possible.