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SafeSense

Digital Discovery Workbook

November 9th, 2018

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Value Proposition

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FDA Regulatory Assessment Questions

1. Who is the user? (e.g., Physician, nurse, patient)

Athletic Coach
Athletic Trainer

2. What is the purpose of the app? (Provide a 1 paragraph description)

The app will be used to display intensity mapping of impacts sustained by football players. The app will keep a record of lifetime impacts and provide real-time alerts if the impacts cross a pre-determined threshold. The pre-determined thresholds will be input based on information from published literature.

The alerts will provide a message stating a particular player(s) has crossed the pre-determined threshold. The athletic coach or trainer will then have the option to navigate the app and check the impacts sustained by the particular player(s). The display options would be:

- A graph showing the impacts (with intensity) sustained by the player(s) over a period of time
- A 3D image of the head showing impact intensities sustained by the player over a period of time

3. What are the inputs to the app? Be specific.

Date, atmospheric temperature, player statistics including name, height, weight, game position

4. What are the outputs of the app? Be specific.

Real time impact intensity mapping

5. If the app provides recommendation for patient treatment, briefly describe the scientific basis for the algorithm used to generate the treatment recommendations.

The app does not provide any recommendation for patient treatment.

6. What is the hardware platform?

App: ios/android

7. How will the software be provided? (e.g, downloaded from App store, pre-installed on hardware platform).

Downloaded from the app store.

Initial Regulatory Review
Donna-Bea Tillman, Ph.D, Biologics Consulting
December 8, 2018

FDA does not regulate protective gear such as football helmets or pads, even though the purpose of such equipment is to prevent injury. Therefore, I believe that if the app were only to provide "intensity mapping of impacts sustained by football players and maintain a record of lifetime impacts", it would not meet the definition of a medical device, and thus would not be regulated by FDA.

The app is also intended to provide a message stating a particular player(s) has "crossed the pre-determined threshold" that will apparently be based on data from the literature. I presume that this threshold reflects the degree of impact that is likely to result in an injury to the player. This feature is a little less clear from a regulatory perspective. However, I think that it is probable that as long as the alert **does not specifically identify a particular disease or condition (**e.g., concussion or TBI), and instead simply informs the user that a potentially harmful impact has occurred, that the app would still probably not meet the definition of a medical device.

Note that FDA has classified software intended to be used to diagnose the presence of a concussion as a medical device, so it would be important the avoid making any direct reference to concussion or TBI.

In regard to the display options, as long as the 3-D image of the head is simply a general model and not an actual radiological image for the player in question, I think that displaying the impact intensities on the image would also not result in the app being regulated as a medical device.

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Use Case Definition

Use case definition contains requirements for the SafeSense app.

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Use Case Definition

Project: Safe Sense – Use Cases
Date: July 18, 2018
Owners: April Kwon, Sarah Jomaa

Goal:

1. *As an athletic trainer, I want to have a tablet application that comprehensively monitors and provides information, in real-time, on impacts football players experience on the field through helmet devices.*
2. *As a medical staff member, I want to have medical-related information collected from the helmet devices so I can make an accurate diagnosis more rapidly in an emergency.*

Coach Use Cases:

1. As a *trainer*, I want to see the home dashboard to show a summary of information about the individual players, the aggregated team data, and the devices that are connected.
2. As a *trainer*, before a game, I want to create a game view easily on the tablet with game participants' information and check the overall connection with devices.
3. As a *trainer*, during the game, I want to get a notice when a player gets a certain level of hits so I can decide whether I will take emergency measures or not.
4. As a *trainer*, I want a few different real-time graphs that compare different variables, such as the location of the hit or intensity level on each sensor on individual helmet gear, that way I can choose a view that I can check important changes on helmets.
5. As a *trainer*, I want to sort or filter collected real-time data for a different player, a group of players based on positions and to have different ranges of presentations of data so I can see the patterns based on different demographic parameters.
6. As a *trainer*, I want to see summary device-related data at the end of the game so I can see if there any need of additional treatment for a player.
7. As a *trainer*, I want to archive the sensor records during previous games so I can look at a player's data over the course of a play versus a season.
8. As a *trainer*, I want to change settings on which information or visualization to be shown in the dashboard.
9. As a *trainer*, I want to check the connection between and real-time data on the bluetooth connection and the battery status of the device so I can in a case replacement is needed.
10. As a *trainer*, I want to have a coach-medical team direct line on the application so I can be connected with the team more quickly in the emergency situation.

Medical staff Use Cases:

1. As medical staff, in an emergency situation, I want to be provided the location, the intensity, and the frequency of the hit(s) as quickly as possible so I can diagnose any possible concussion and take instant medical action.
2. As medical staff, I want to be informed about personal medical information, treatment history of a player that I should treat.

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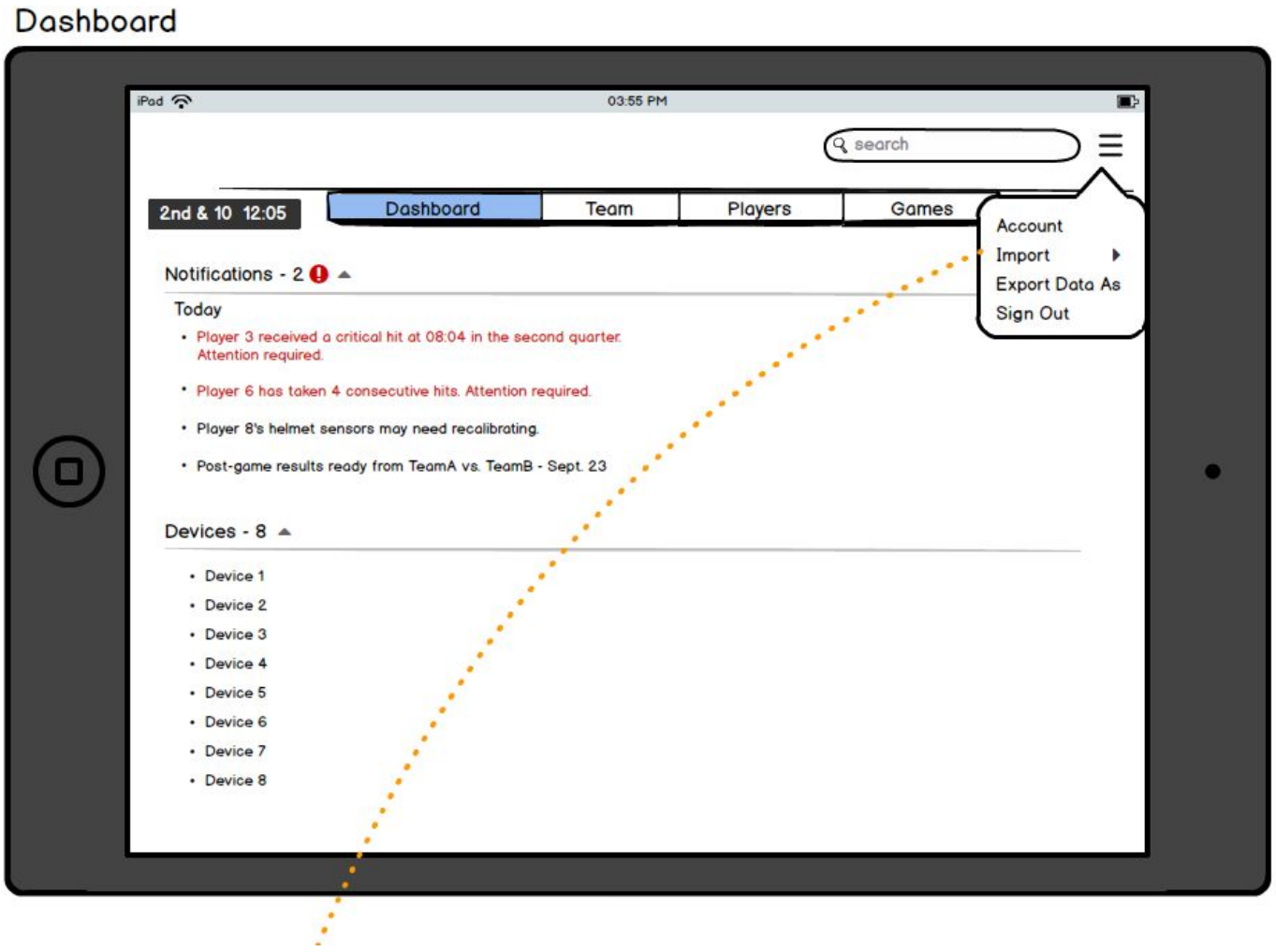
User Comps

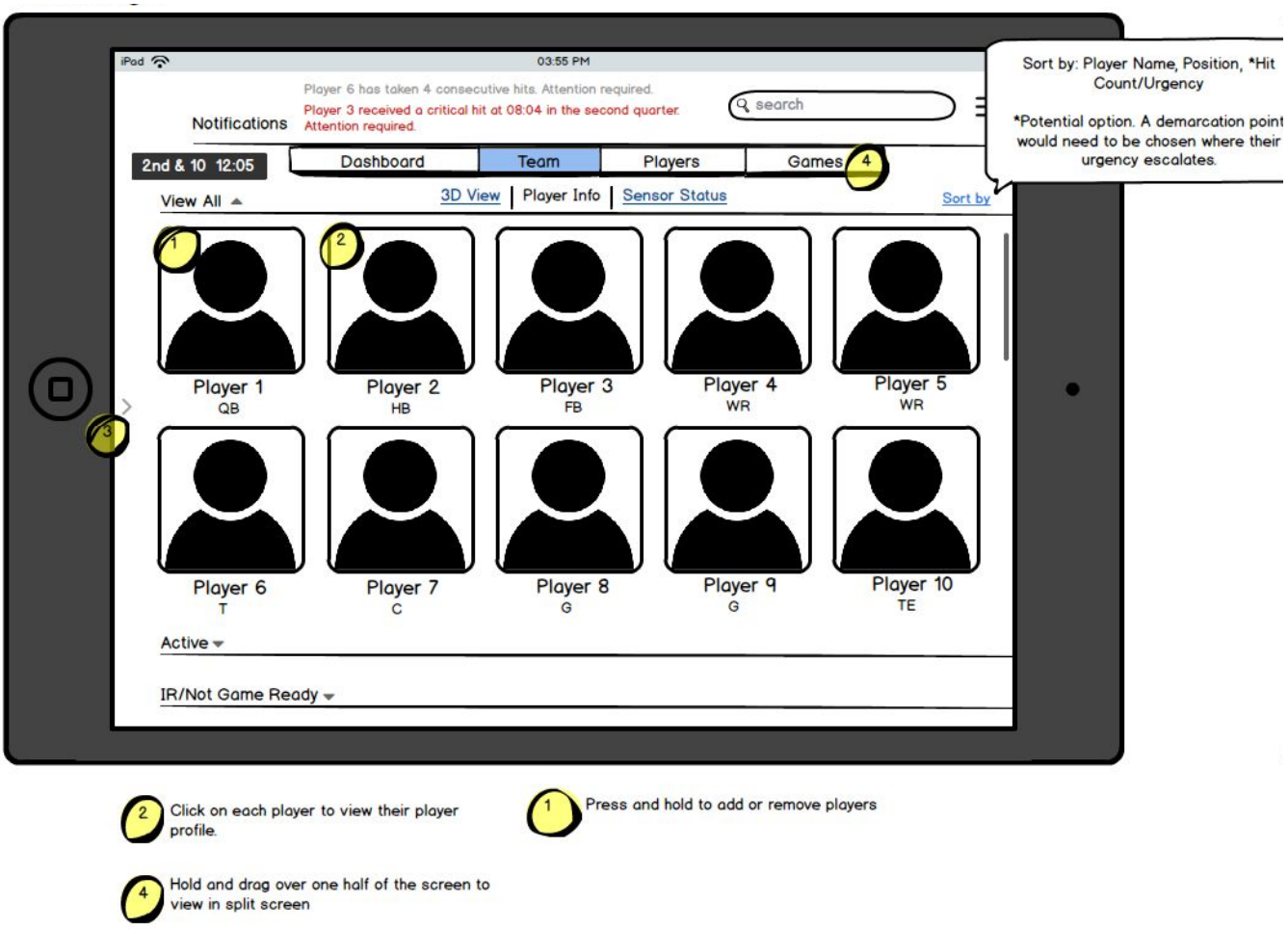
User Comps are provided to allow an inventor the opportunity to review the navigation of the application's flow.

Low-Fi Prototype 1

Dashboard



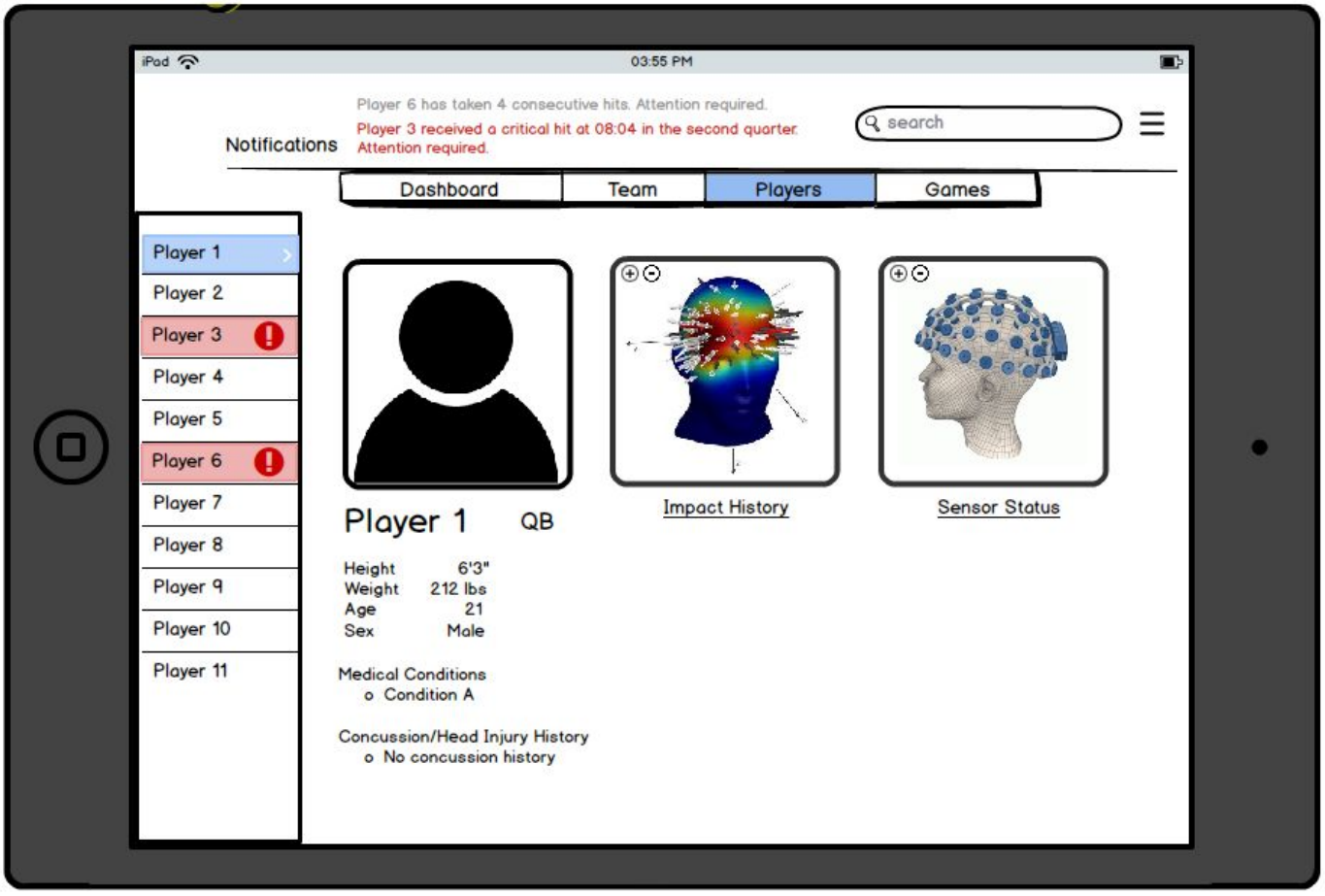
Team Page


iPad
03:55 PM
Player 6 has taken 4 consecutive hits. Attention required.
Player 3 received a critical hit at 08:04 in the second quarter. Attention required.
Notifications
search
2nd & 10 12:05
Dashboard
Team
Players
Games
4
View All
3D View | Player Info | Sensor Status
Sort by
Sort by: Player Name, Position, *Hit Count/Urgency
*Potential option. A demarcation point would need to be chosen where their urgency escalates.
1
2
3
Player 1 QB
Player 2 HB
Player 3 FB
Player 4 WR
Player 5 WR
Player 6 T
Player 7 C
Player 8 G
Player 9 G
Player 10 TE
Active
IR/Not Game Ready
2 Click on each player to view their player profile.
1 Press and hold to add or remove players
4 Hold and drag over one half of the screen to view in split screen

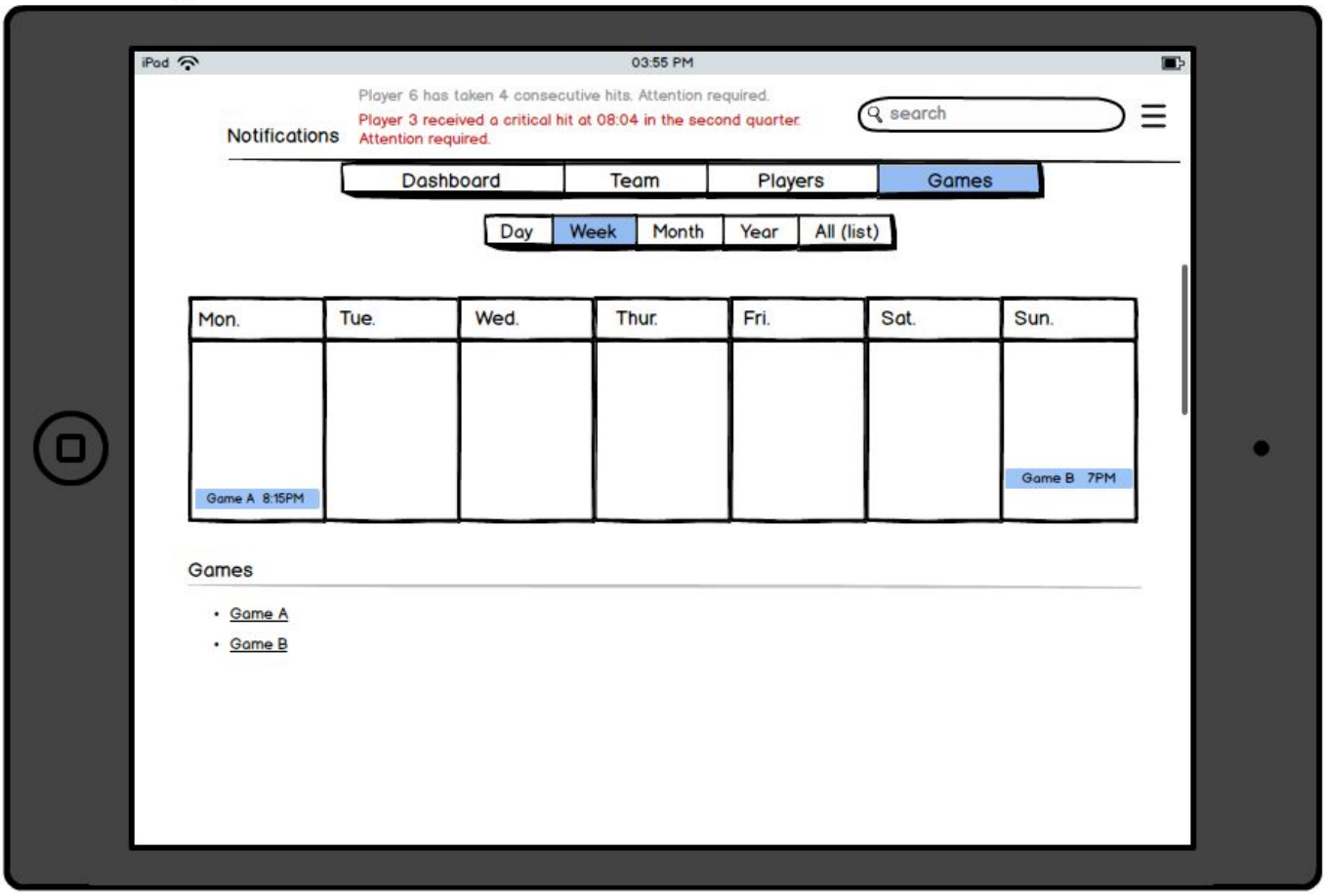
Double tapping on a player's profile will expand it to a 4-panel view. Press and drag inside each panel to rotate 3D model in the direction you desire. Drag one panel to another panel to swap places. Drag edges to make the panel larger or smaller. Double tap a view screen to fill the whole panel. Tap outside or on the minus sign to minimize to normal size.

View Ethmoid, Sphenoid, Occipital, Frontal, and Temporal sections of the skull. Tap once to view the slider and play/pause button, use them to go back and view a certain time.

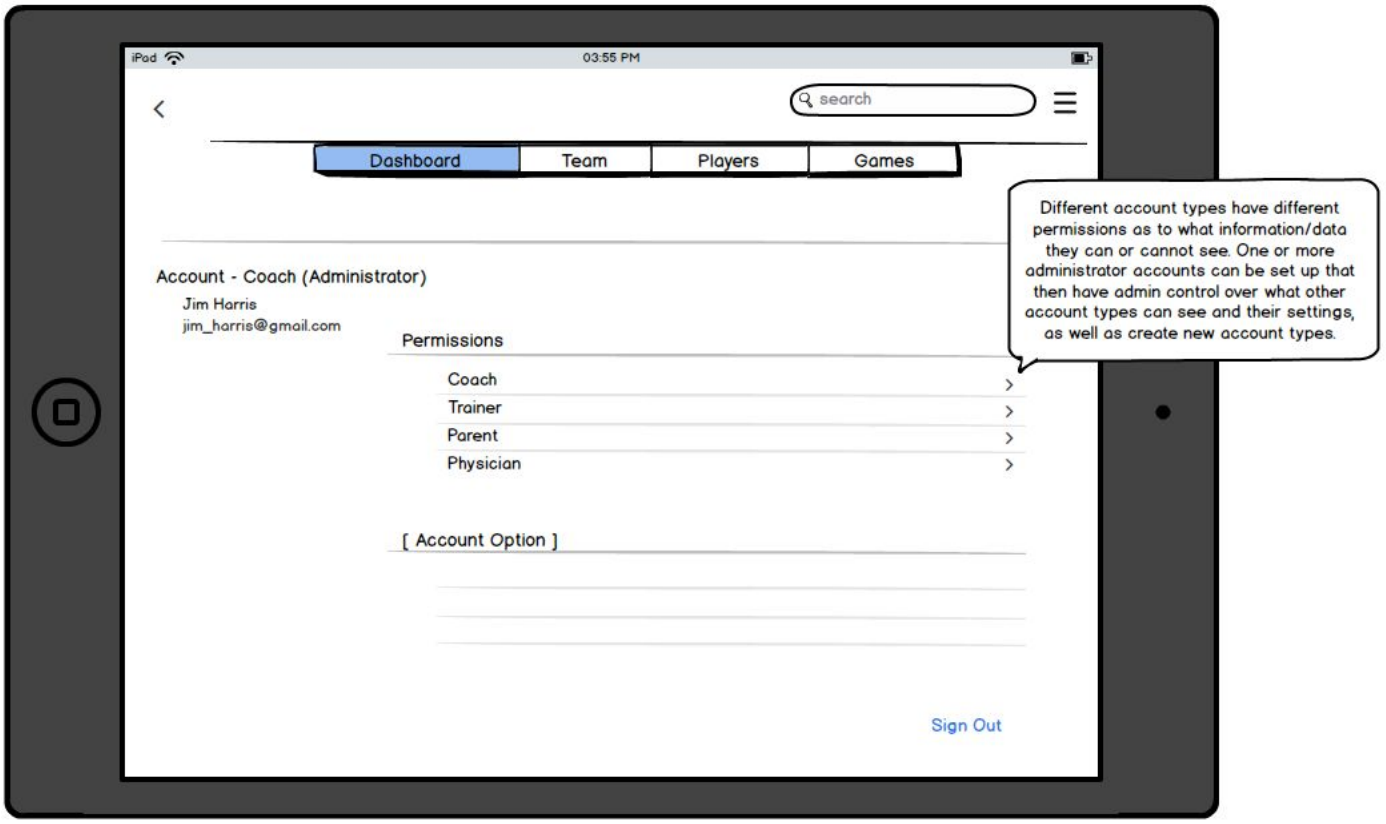
Player Page


iPad
03:55 PM
Player 6 has taken 4 consecutive hits. Attention required.
Player 3 received a critical hit at 08:04 in the second quarter. Attention required.
Notifications
search
Dashboard
Team
Players
Games
Player 1
Player 2
Player 3
Player 4
Player 5
Player 6
Player 7
Player 8
Player 9
Player 10
Player 11
Player 1 QB
Height 6'3"
Weight 212 lbs
Age 21
Sex Male
Medical Conditions
o Condition A
Concussion/Head Injury History
o No concussion history
Impact History
Sensor Status

Games Page


iPad
03:55 PM
Player 6 has taken 4 consecutive hits. Attention required.
Notifications
Player 3 received a critical hit at 08:04 in the second quarter. Attention required.
search
Dashboard
Team
Players
Games
Day
Week
Month
Year
All (list)
Mon.
Tue.
Wed.
Thur.
Fri.
Sat.
Sun.
Game A 8:15PM
Game B 7PM
Games
Game A
Game B

Settings


iPad
03:55 PM
search
Dashboard
Team
Players
Games
Different account types have different permissions as to what information/data they can or cannot see. One or more administrator accounts can be set up that then have admin control over what other account types can see and their settings, as well as create new account types.
Account - Coach (Administrator)
Jim Harris
jim_harris@gmail.com
Permissions
Coach
Trainer
Parent
Physician
[Account Option]
Sign Out

Low-Fi Prototype 2

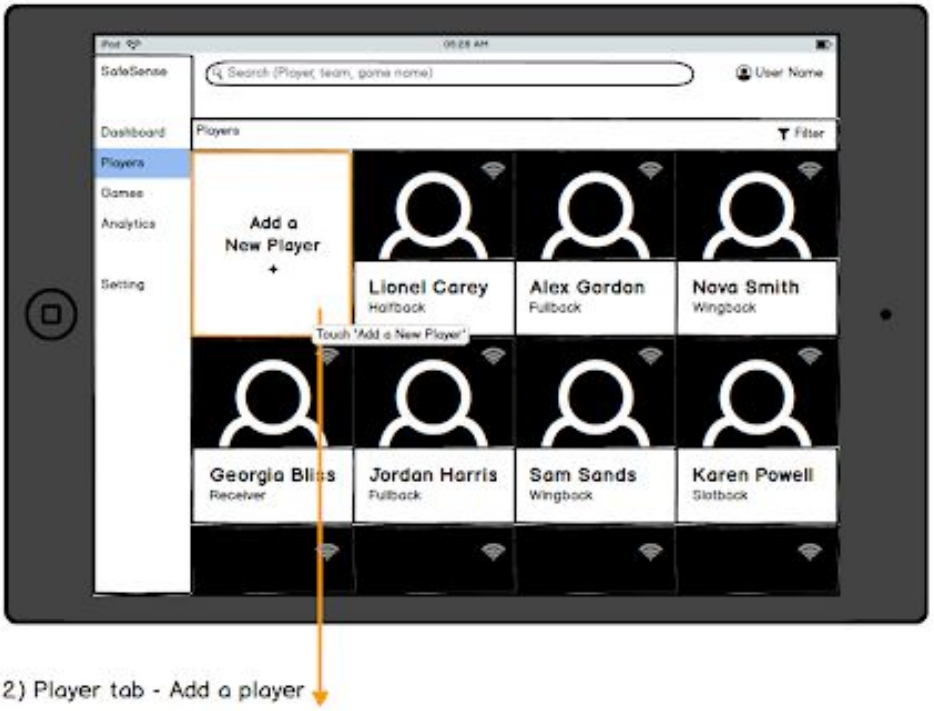
1) Home Dashboard (Coach/Trainer & Parent view)

1) Home Dashboard - Coach/Trainer View

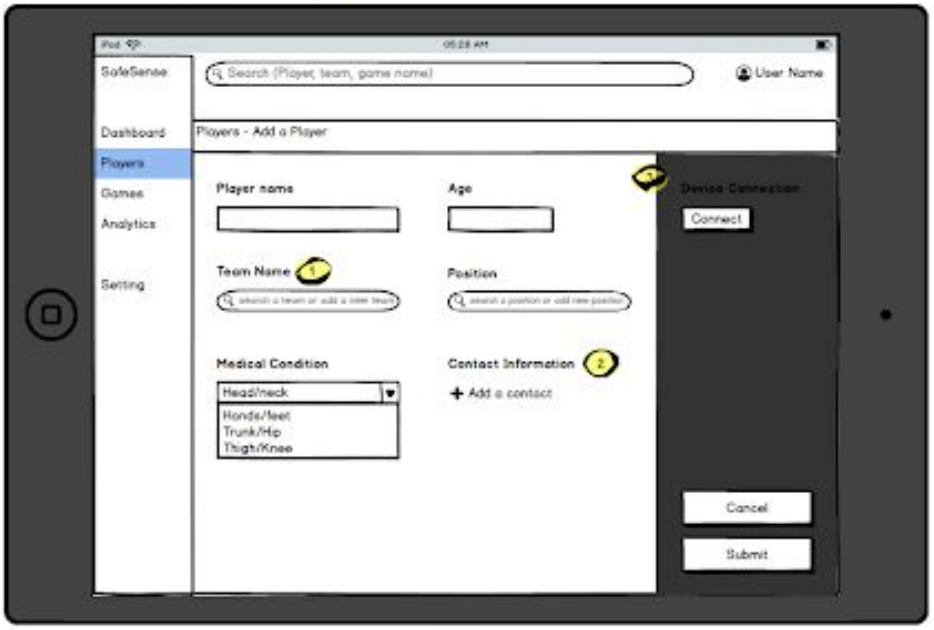
2) Home Dashboard - Parent View

1 The home screen can be customized by users:
- Coach/trainer view: The summary of the team/selected players
- Parent view: A single player and related game information

2) Player Page (Add a player)



2) Player tab - Add a player

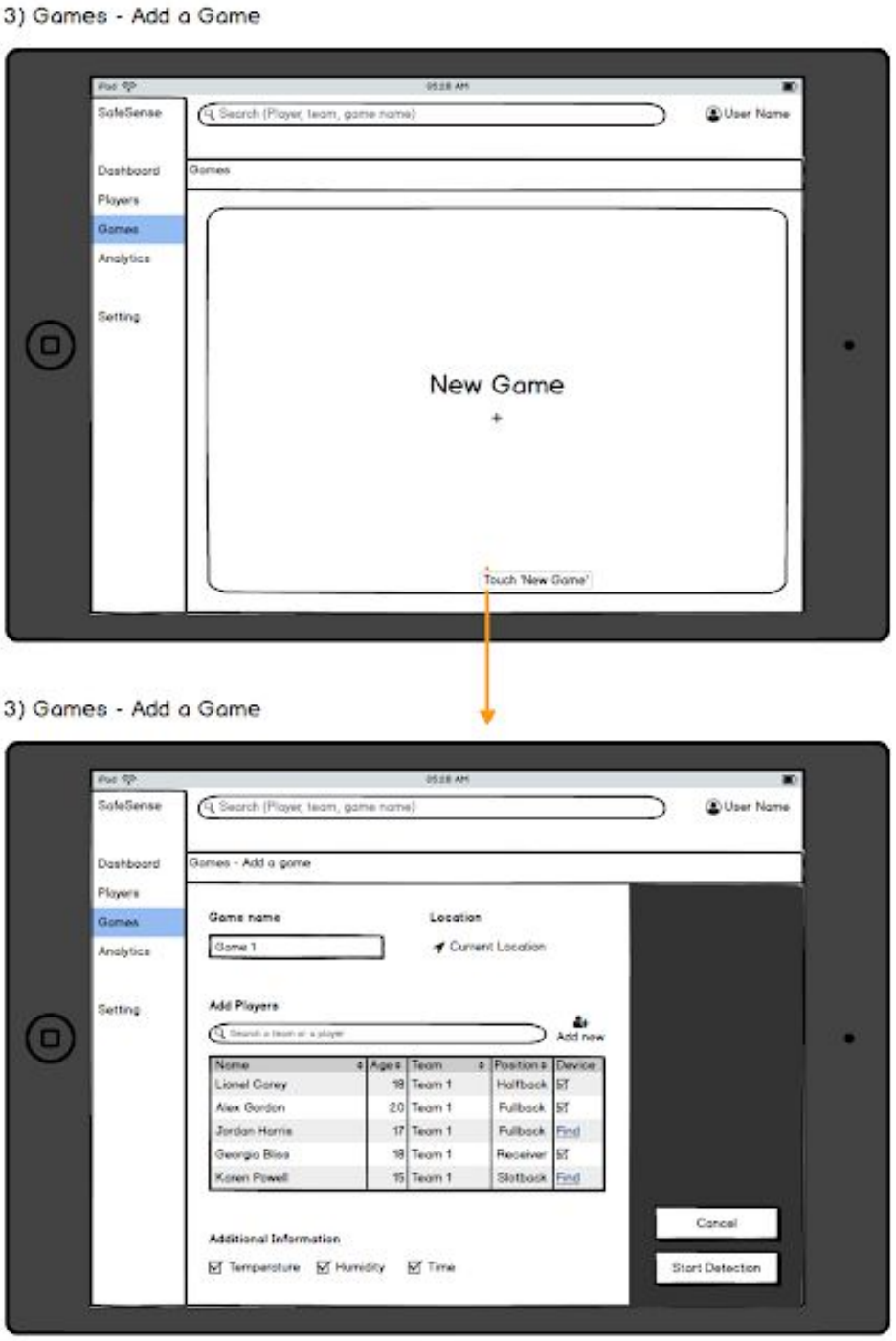


1 Team information is stored in local database

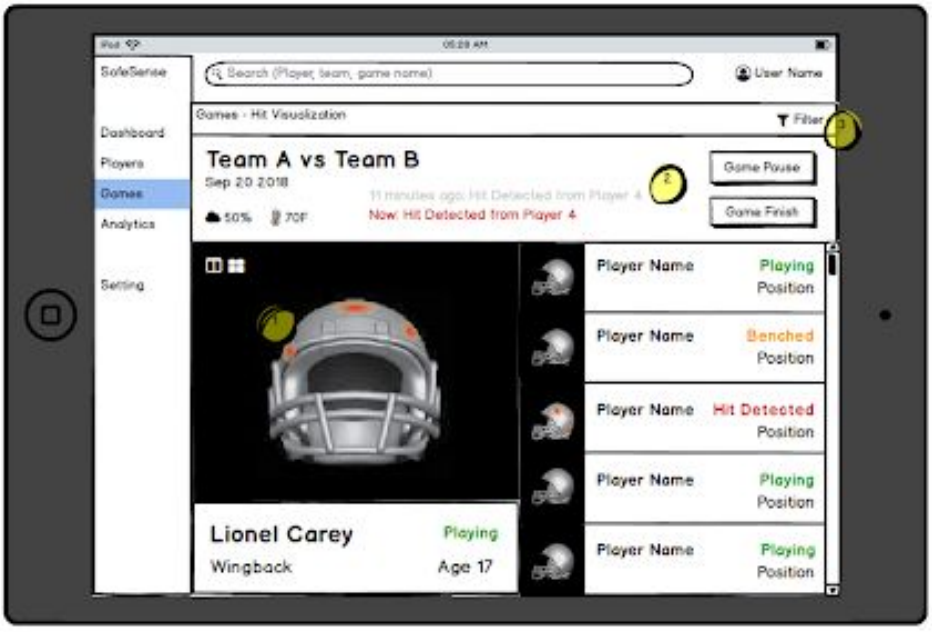
2 Contact information can connect to a player's coaches/ physicians/parents

3 The device can be connected to the application either during player profiling, or before a game

3) Game Page (Start game tracking)



3-1) During a game

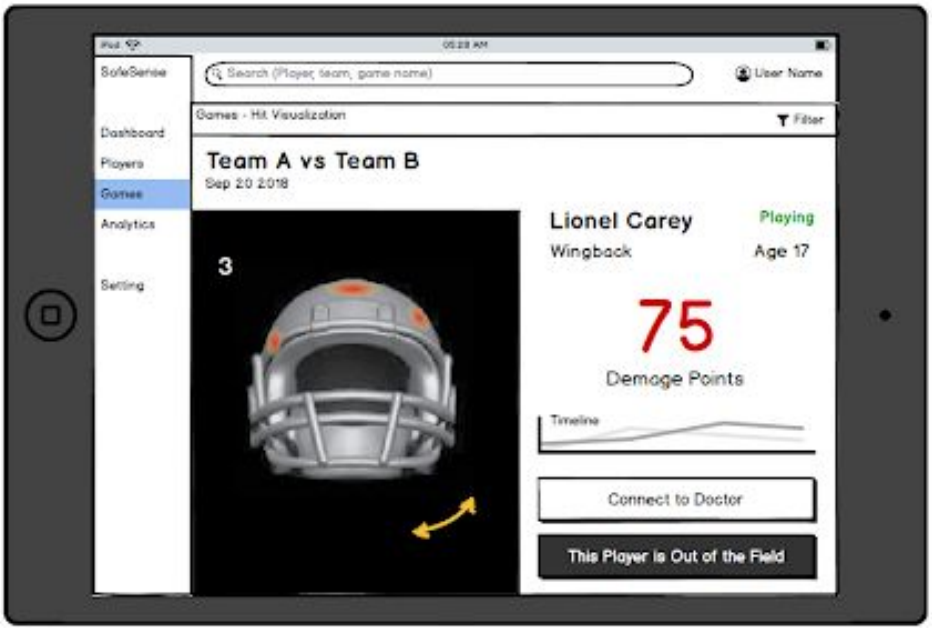


The sign of the hit can be simplified

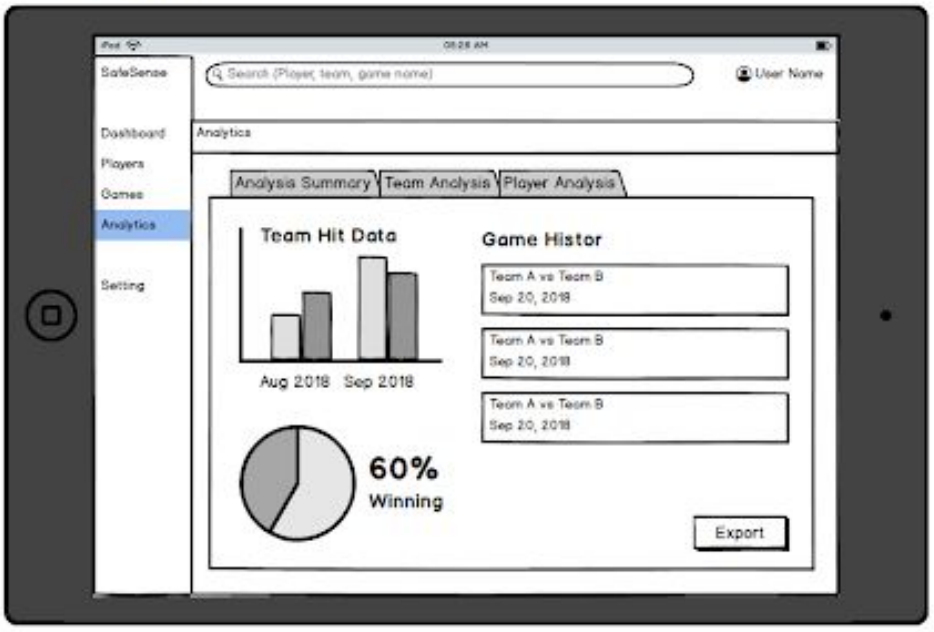
Real-time device activities (hit detection, device disconnection, etc.) are notified on the top menu

The filters can be based on the available parameters in player profiling page as well as the number/intensity of the hit detected

1-2) Hit Visualization (Individual View)



4) Analytics & Setting



2) Setting