O.R. BLACKBOX

ECE1778 Final Report

Word Count: 1992 (+ 346 words for Apper Context)

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Introduction

Each year, between 9,000 and 24,000 Canadians die as a result of preventable medical errors[1]. The operating room (OR) is a high-risk environment, yet the factors that contribute to medical errors within this context remain poorly understood[2]. The goal of the *OR Blackbox* is to provide a better understanding of how and why surgical complications occur. Our app displays multiple feeds from the OR on a single interface – similar to the aviation blackbox that is used to record flight data. This integrated interface enables surgeons to analyze a surgical procedure from multiple perspectives simultaneously, thus helping them pinpoint the multiple factors that contribute to adverse outcomes in the OR.

We designed and developed a user-friendly interface for our blackbox app using the iPad mobile platform. This app displays the following feeds from the operative environment:

1. Wide-angled view of the OR
2. Endoscopic camera view
3. Vital sign data from the anesthesia monitor
4. Audio from a ceiling microphone in the OR

To evaluate surgical performance, the app contains validated surgical checklists and global rating scales.

Overall Design

Our block diagram uses the Model-View-Controller architectural pattern recommended by Apple. Figure 1 shows the high-level block diagram for the overall design of our app.

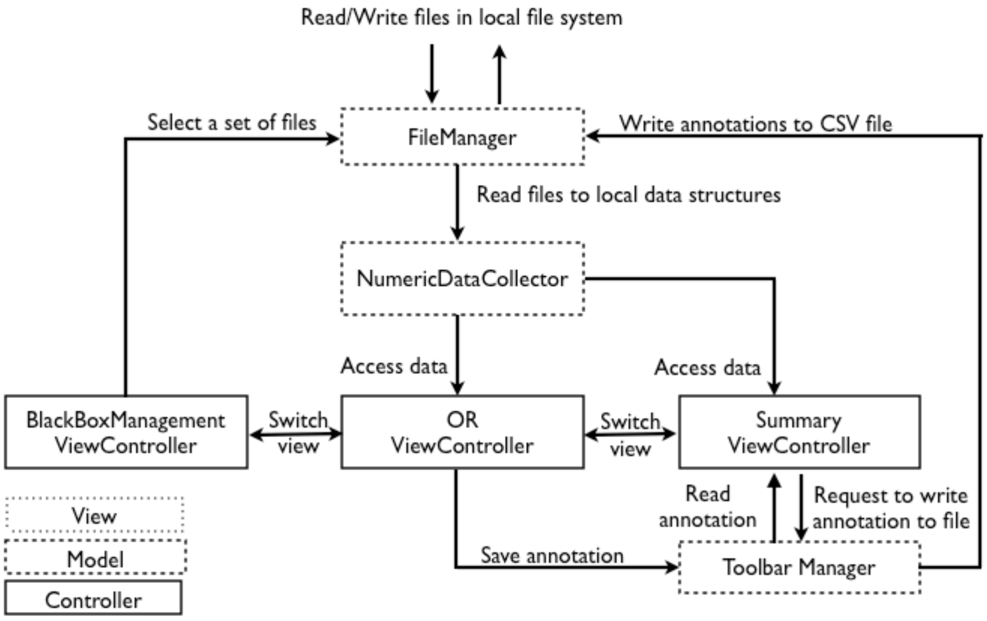


FIG 1. High-level block diagram.

Models

1. `FileManager`

Reads from and writes to the file system, manages iTunes file import/export

2. `NumericDataCollector`

Reads data from files opened by FileManager and keeps a copy of the data in a local data structure

3. `ToolbarManager`

Stores all annotations that have been recorded in the OR main view.

All models are implemented with the singleton design pattern, in which a single instance of an object can be retrieved by a class method. Since there is only one instance for each model object in this app, the singleton pattern provides a convenient way to access the model instances.

View Controller & Views

The major views in this app are (1) BlackBox Management view, (2) OR view, and (3) Summary view.

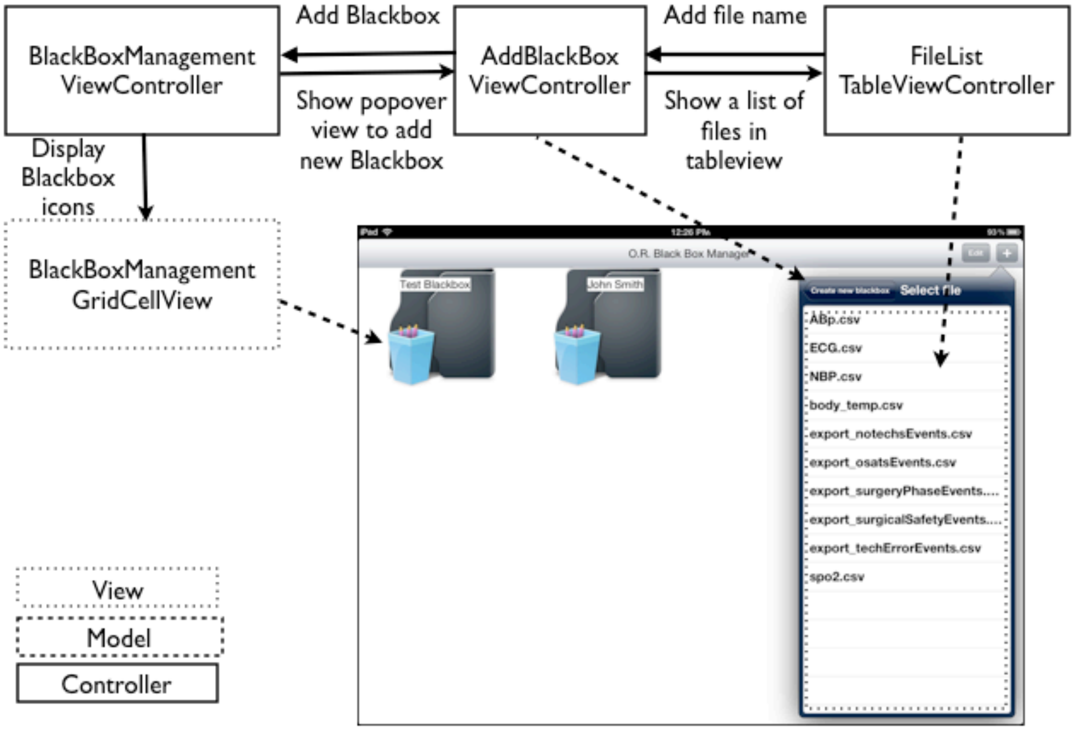

Add Blackbox
Add file name
BlackBoxManagement ViewController
AddBlackBox ViewController
FileList TableViewController
Show popover view to add new Blackbox
Show a list of files in tableview
Display Blackbox icons
BlackBoxManagement GridCellView
O.R. Black Box Manager
Edit
+
Test Blackbox
John Smith
Create new blackbox
Select file
ABp.csv
ECG.csv
NBP.csv
body_temp.csv
export_notechsEvents.csv
export_osatsEvents.csv
export_surgeryPhaseEvents....
export_surgicalSafetyEvents....
export_techErrorEvents.csv
spo2.csv
View
Model
Controller

FIG 2. BlackBoxManager ViewController.

1. BlackBoxManager ViewController

Figure 2 shows the architecture of the app under `BlackBoxManager ViewController`, which handles the overall layout in this view.

- `BlackBoxMangermentGridCellView` draws the view for each blackbox folder.
- `AddBlackBox ViewController` draws the popover window for the user to create a new blackbox folder.
- `FileList TableViewController` shows a list of files in file system in a table view.

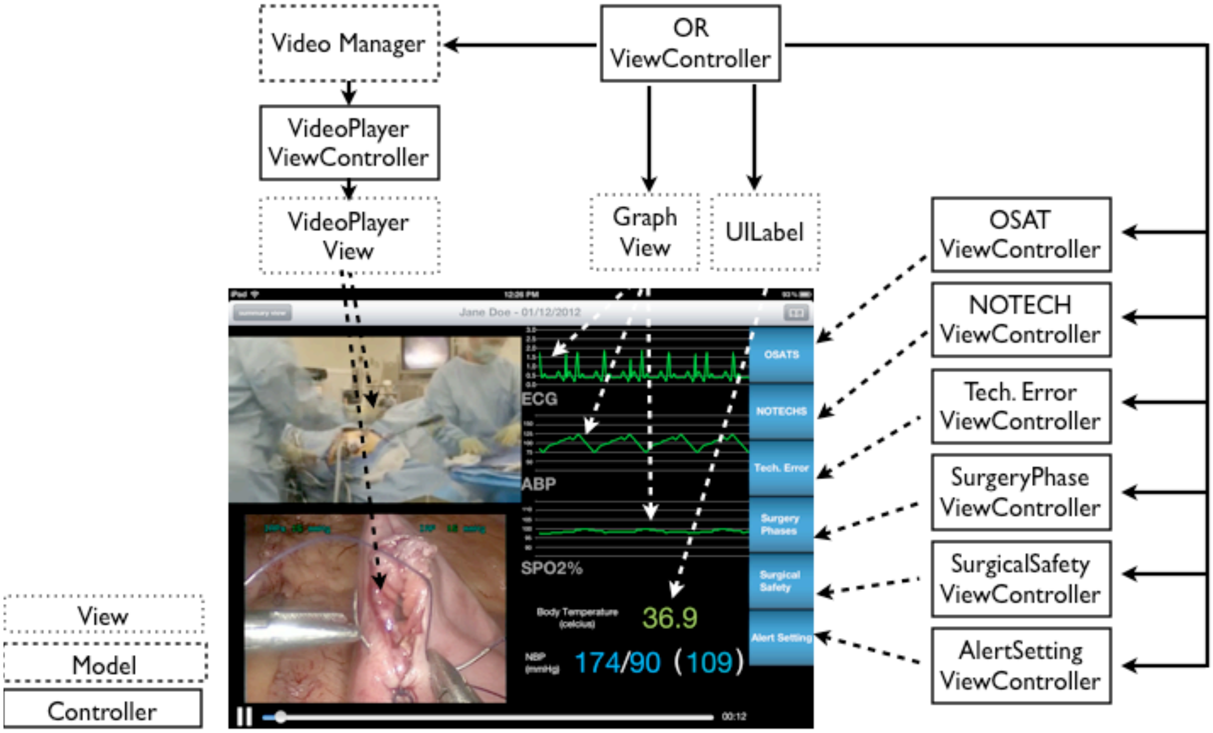


FIG 3. OR View Controller.

2. `OR ViewController`

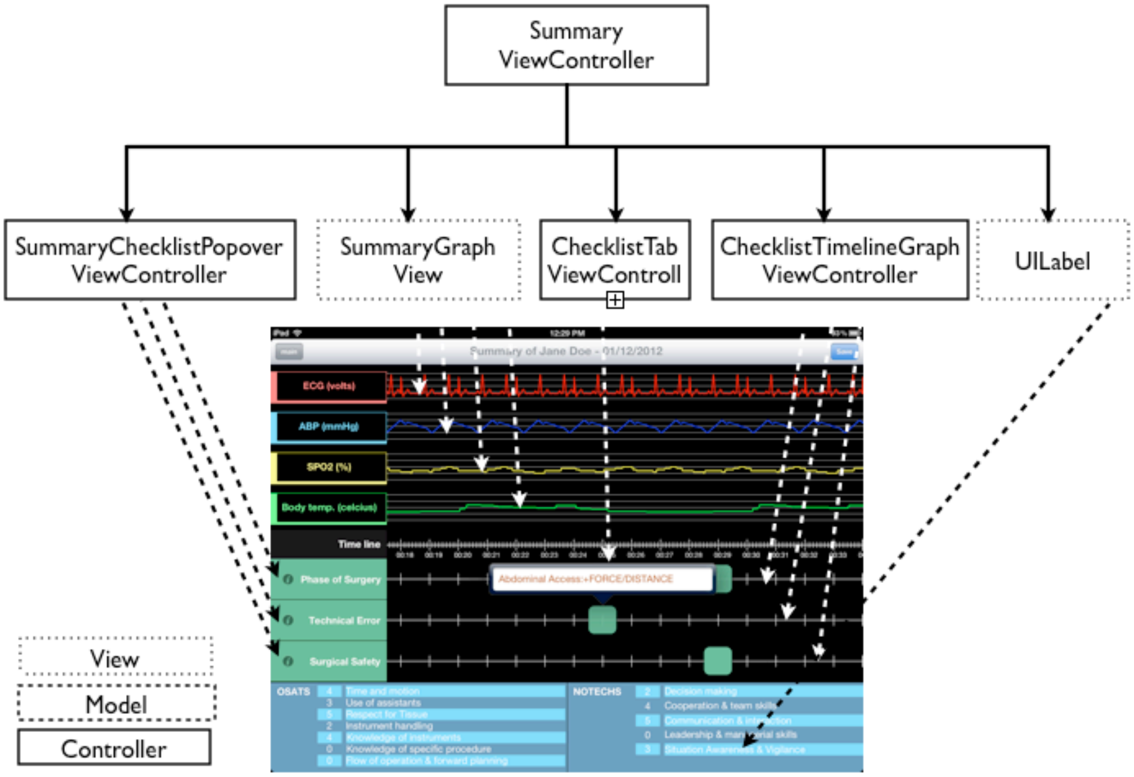
Figure 3 shows the architecture of the app under `OR ViewController`, which handles the main view for this app.

- `Video Manager` handles the simultaneous display of two video feeds. One of the videos is played by calling the default video player in iOS (`MPPlayerController`), and the other video is handled by `VideoPlayer ViewController`, which uses AVFoundation library APIs to display and synchronize the secondary video.

- `Graph View` renders dynamic waveforms in real-time by moving segments forward in the graph. The waveform history is not stored in these views.

- Body temperature and non-invasive blood pressure (NBP) values are `UILabel` objects that update periodically.

- `(OSATS, NOTECHS, Tech Error, SurgeryPhase, SurgicalSafty, AlertSetting) ViewController`: These controllers handle the subviews for their corresponding checklists.



OSATS		
	4	Time and motion
	3	Use of assistants
	5	Respect for Tissue
	2	Instrument handling
	4	Knowledge of instruments
	0	Knowledge of specific procedure
	0	Flow of operation & forward planning

NOTECHS		
	2	Decision making
	4	Cooperation & team skills
	5	Communication & interaction
	0	Leadership & managerial skills
	3	Situation Awareness & Vigilance

FIG 4. Summary View Controller

3. SummaryViewController

Figure 4 shows the architecture of the block diagram under `Summary ViewController`, which handles the summary view.

- `SummaryChecklistPopover ViewController` handles the popover view when the user taps the info icon.

- `SummaryGraph View` is rendered dynamically in the background since there is no upper bound for the duration of the video feeds. The first 20 seconds of the waveforms are rendered when the summary view is first launched. As the user scrolls the waveform, one minute of graph data is rendered in the background.

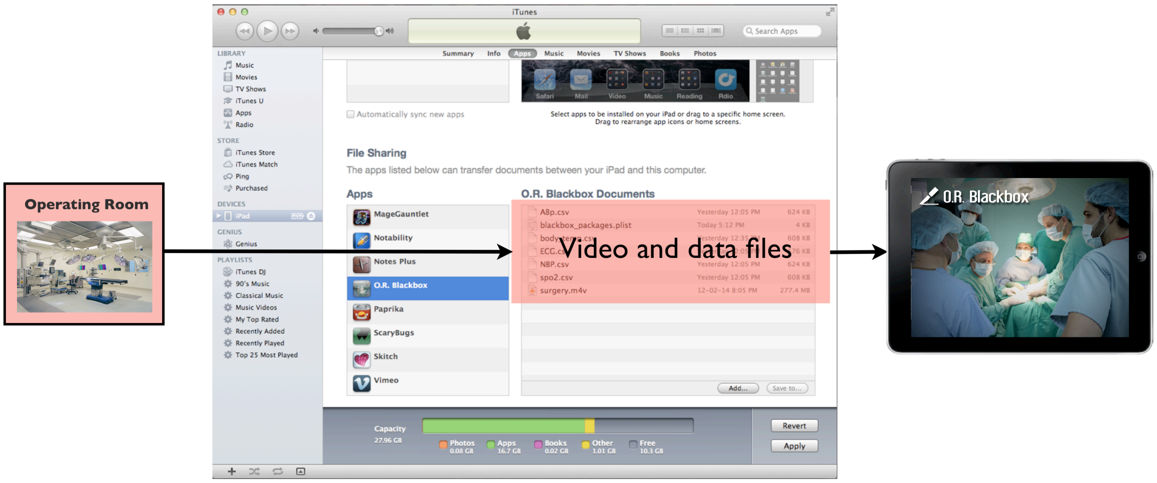
- `ChecklistTab ViewController` is added as a green box to the checklist timeline whenever an event or error is recorded in the main view. When the user taps on a green box, this view controller will retrieve a list of corresponding errors or events at that point in the surgery and display them in a popover window.
- `ChecklistTimelineGraph ViewController` draws the grid line as a placeholder for the green boxes.

- `UILabel`: The tables that show the global rating scales are labels. Their values are read from Toolbar Manager.

Statement of Functionality

Step 1: iTunes Data File Import

The user must first import the video and vital sign data files of the surgical procedure into the app folder via iTunes. Source data files must be in CSV format for vital signs and .mov, .mp4, .m4v, or .3gp format for videos.



□ Automatically sync new apps

Select apps to be installed on your iPad or drag to a specific home screen.
Drag to rearrange app icons or home screens.

File Sharing

The apps listed below can transfer documents between your iPad and this computer.

Apps: MageGauntlet, Notability, Notes Plus, O.R. Blackbox, Paprika, ScaryBugs, Skitch, Vimeo

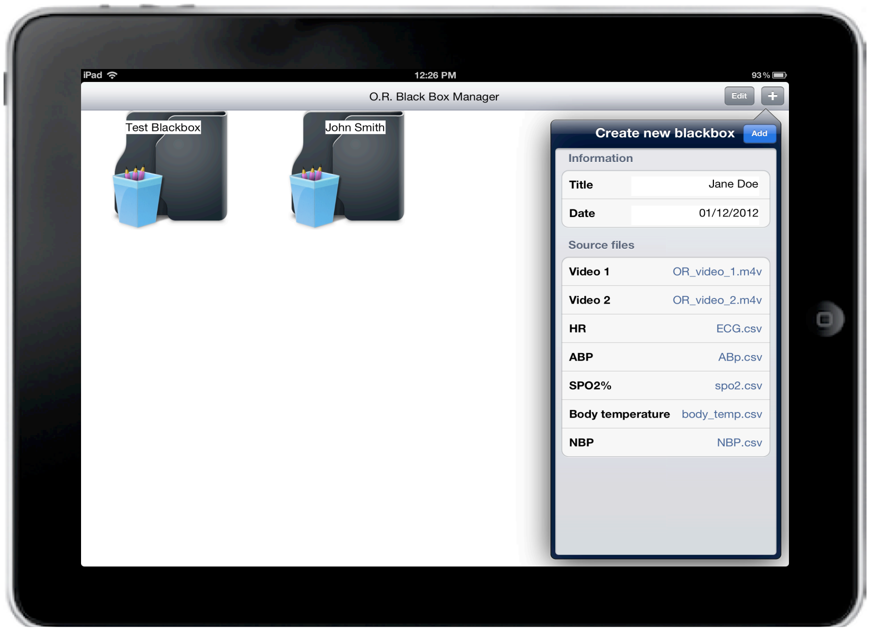
O.R. Blackbox Documents

ABp.csv	Yesterday 12:05 PM	624 KB
blackbox_packages.plist	Today 5:12 PM	4 KB
body_temp.csv	Yesterday 12:35 PM	608 KB
ECG.csv	Yesterday 12:05 PM	76 KB
NBP.csv	Yesterday 12:05 PM	624 KB
spo2.csv	Yesterday 12:05 PM	608 KB
surgery.m4v	12-02-14 8:05 PM	277.4 MB

Capacity 27.96 GB — Photos 0.08 GB, Apps 16.7 GB, Books 0.02 GB, Other 1.01 GB, Free 10.3 GB

Step 2: O.R. Blackbox Management

Upon launch, the user is directed to the file management section of the OR blackbox. The user can create a new blackbox folder, which associates a set of imported data files to a specific surgical procedure. After entering the title and date of the blackbox folder, the user assigns each data feed to one of the files imported via iTunes. The user can delete a blackbox folder by tapping the "Edit" button on the top toolbar, which causes a red "X" button to be overlaid on each folder. To load any blackbox into the main view, the user simply taps the icon of their selected blackbox.



Information

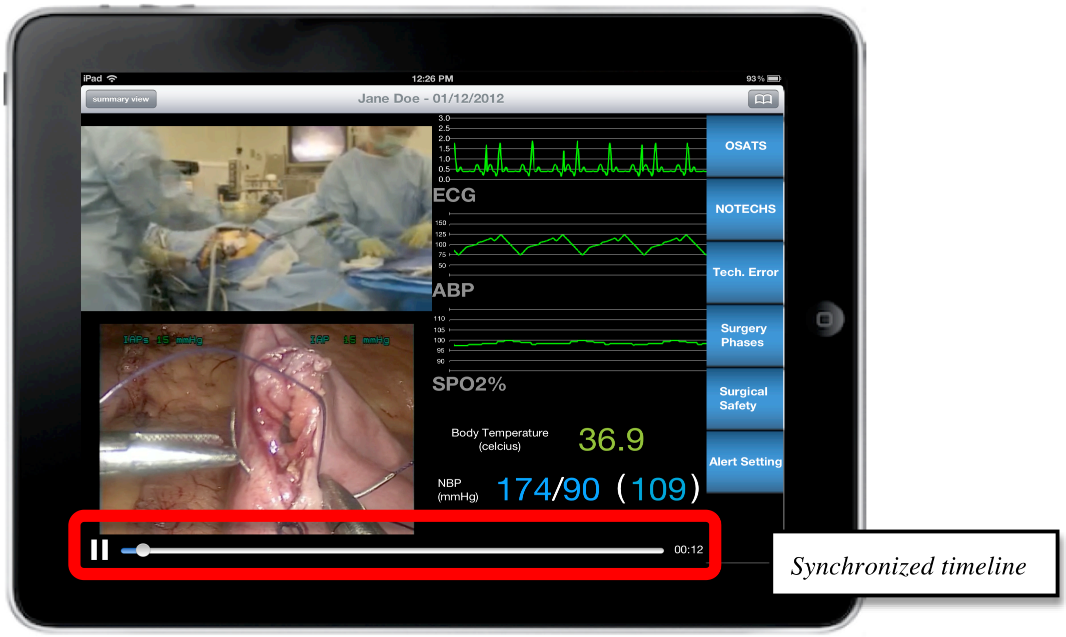
Title	Jane Doe
Date	01/12/2012

Source files

Video 1	OR_video_1.m4v
Video 2	OR_video_2.m4v
HR	ECG.csv
ABP	ABp.csv
SPO2%	spo2.csv
Body temperature	body_temp.csv
NBP	NBP.csv

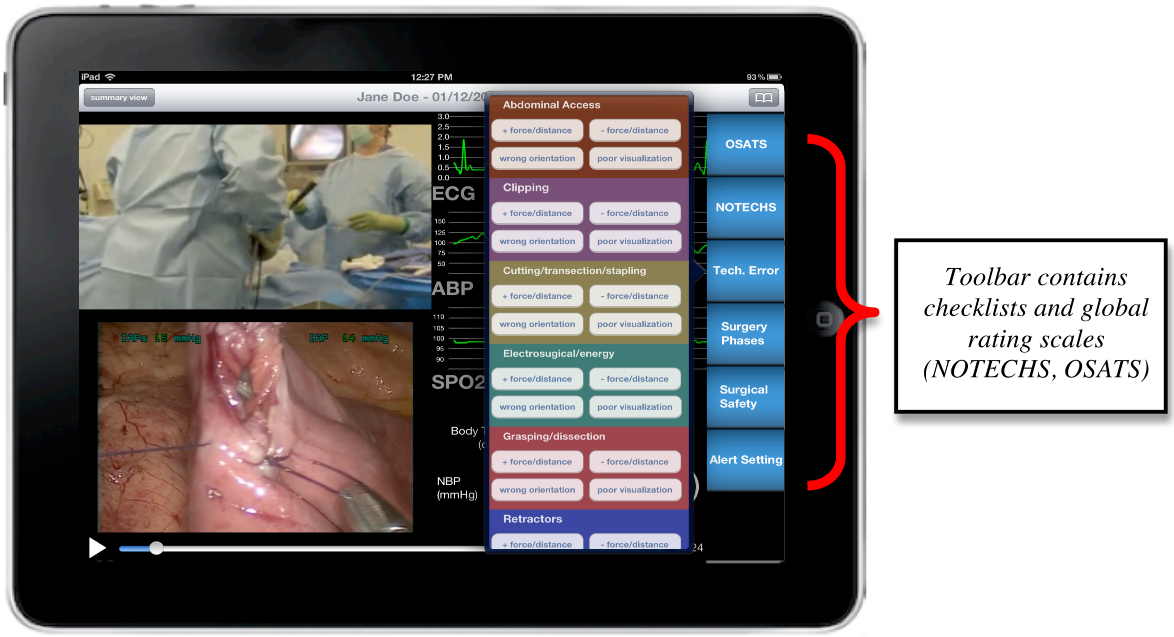
Step 3: Main View

The main view displays the following feeds from the OR: endoscopic camera video, OR video and audio feed, electrocardiogram (ECG), arterial blood pressure (ABP), oxygen saturation monitor (SPO2%), body temperature, and non-invasive blood pressure (NBP). These feeds are played in synchronization and can be scrubbed forward and backward or paused using the controls along the bottom of the screen.



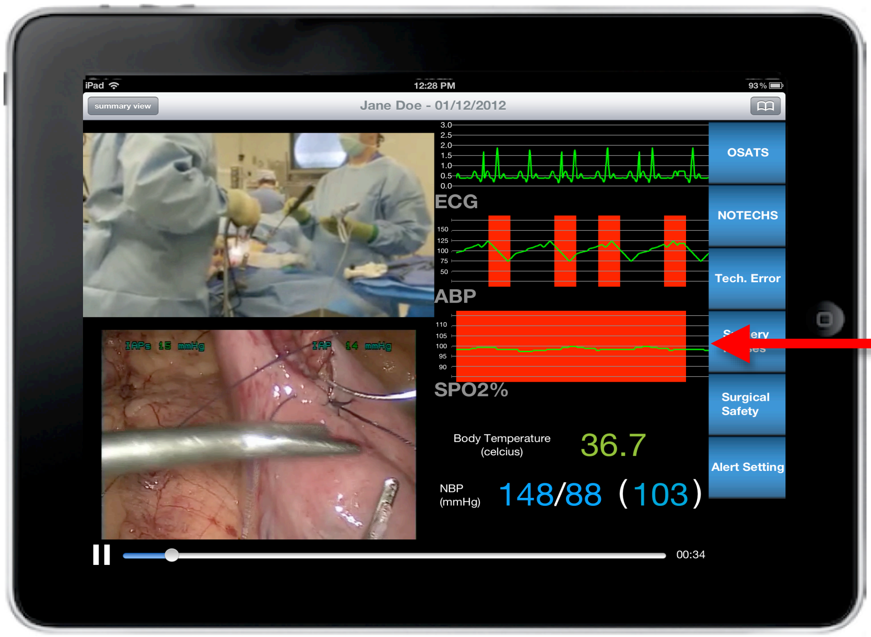
Synchronized timeline

During playback, the user can evaluate the performance of the surgical team using surgical checklists and global rating scales found on the toolbar. All notations made using the toolbar checklists are logged to a data model for display in the summary view.



Toolbar contains checklists and global rating scales (NOTECHS, OSATS)

The alert setting on the toolbar allows the user to configure alerts when vital sign data points exceed a specified threshold. Once configured, sections of the graphs that exceed these thresholds are highlighted in red.

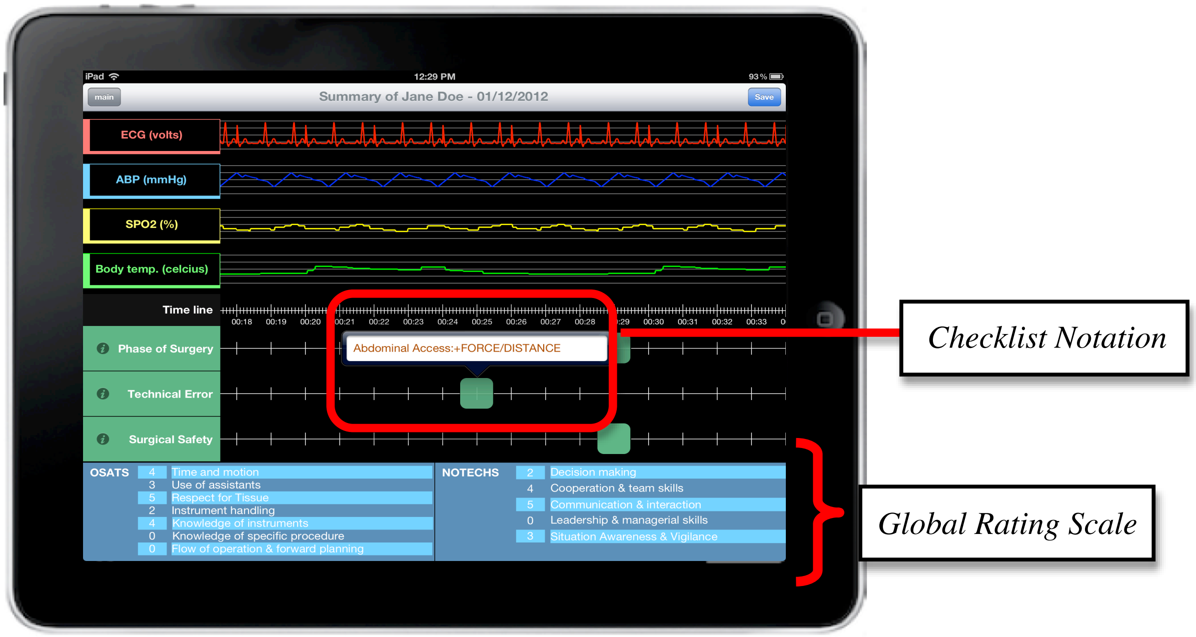


Alert: Arterial blood pressure (ABP) values have exceeded the threshold levels.

Once evaluation is complete, the user can tap the “summary view” button at the top left to load the final summary view.

Step 4: Summary View

The summary view displays vital sign data and time-stamped checklist events as recorded by the user to a single master timeline (scaled in seconds). Each checklist notation is represented as a green block on the timeline. When a block is tapped, a popover appears displaying the notations made at that point in the surgery. Tapping the information icon on the left side of the timeline displays a legend that lists all possible notation values. At the bottom of the screen, data from the global rating scales, such as the Objective Structured Assessment of Technical Skills (OSATS) and NOn TECHnical Skills (NOTECHS), are displayed. These scales indicate overall performance during a surgical procedure, and thus are not displayed at specific points in the timeline.



Summary of Jane Doe - 01/12/2012

ECG (volts)

ABP (mmHg)

SPO2 (%)

Body temp. (celcius)

Phase of Surgery

Technical Error

Surgical Safety

Abdominal Access:+FORCE/DISTANCE

OSATS		
	4	Time and motion
	3	Use of assistants
	5	Respect for Tissue
	2	Instrument handling
	4	Knowledge of instruments
	0	Knowledge of specific procedure
	0	Flow of operation & forward planning

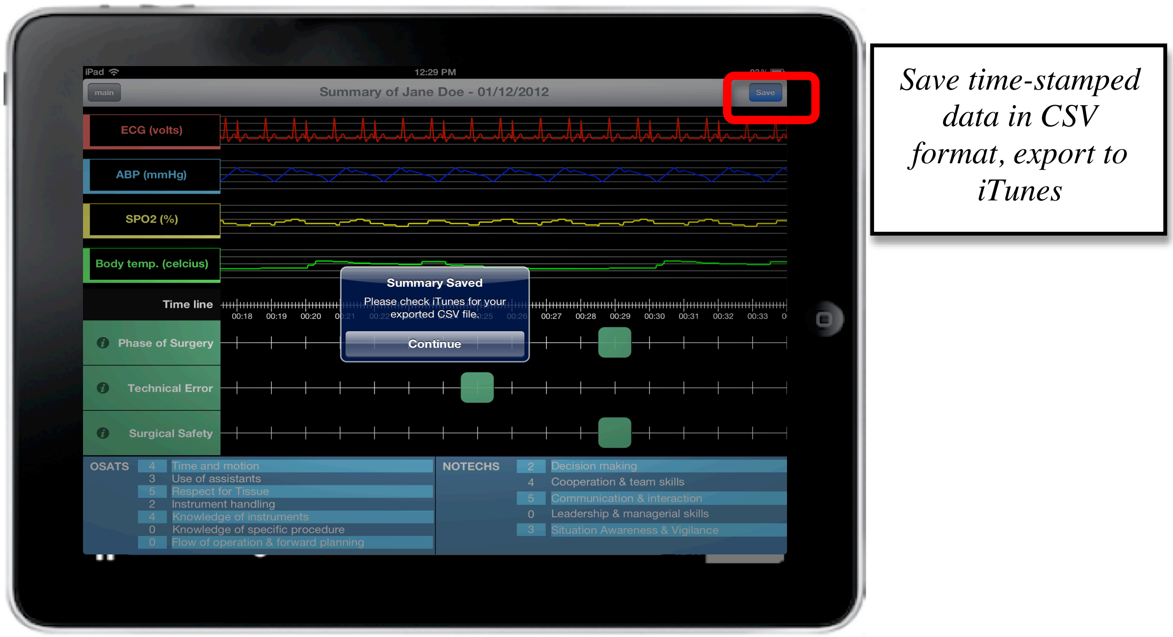
NOTECHS		
	2	Decision making
	4	Cooperation & team skills
	5	Communication & interaction
	0	Leadership & managerial skills
	3	Situation Awareness & Vigilance

Checklist Notation

Global Rating Scale

Summary View

Once the user is finished reviewing the data, their notations can be exported to CSV format by tapping the “Save” button at the top right of the screen. CSV files are generated for the checklists and global rating scales, which can be uploaded to a computer via iTunes in the same file sharing section where data files were originally imported. These exported files can then be analyzed using statistical analysis software.



Summary of Jane Doe - 01/12/2012

ECG (volts)

ABP (mmHg)

SPO2 (%)

Body temp. (celcius)

Phase of Surgery

Technical Error

Surgical Safety

Summary Saved

Please check iTunes for your exported CSV file.

OSATS		
	4	Time and motion
	3	Use of assistants
	5	Respect for Tissue
	2	Instrument handling
	4	Knowledge of instruments
	0	Knowledge of specific procedure
	0	Flow of operation & forward planning

NOTECHS		
	2	Decision making
	4	Cooperation & team skills
	5	Communication & interaction
	0	Leadership & managerial skills
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Save time-stamped data in CSV format, export to iTunes

Lessons Learned

Ethics Approval

The use of recorded OR material for evaluation of surgical performance raises ethical concerns. Recording any material that identifies the patient or surgical staff requires approval from the Research Ethics Board (REB) and consent from all individuals involved. If we were to start the app project again, we would apply for approval from the REB to record OR videos and vital sign data at St. Michael's Hospital. REB approval would have allowed us to test the app with real data from the OR, rather than using simulated vital sign data and videos found online.

Abnormal Vital Sign Patterns

In our original proposal, we planned to create a vital sign alert that notifies the user when heart rate, blood pressure, or oxygen saturation of the patient reaches dangerous levels. At first, we wanted to set threshold values for the alerts using the normal range of vital signs of a typical patient. However, we quickly learned that the definition of "normal vital signs" differs significantly across the patient population. To solve this problem, we have allowed the user to customize the upper and lower threshold values for each vital sign feed to account for variation in patient physiology.

Automatic Reference Counting (ARC) for Objective-C

Using ARC, the compiler is responsible for all memory management in Objective-C, as opposed to the developer manually creating and releasing objects in memory. In most cases, developers can use ARC without understanding what it does in the background. However, some online libraries exclude ARC, and problems related to memory management can be difficult to debug without a thorough understanding of how ARC works. If we started this project again, we would make sure that both programmers understand ARC thoroughly before beginning the programming.

Modular Design and Performance Optimization

We proposed a live mode and post-operative review mode for this app, but only implemented the *review mode* in this course. We tried to design the app in a modular way such that only the file-loading interface would need to be changed when adding the live streaming mode. However, we should have taken advantage of the fact that we have access to the complete data set in review mode. In review mode, dynamic rendering in the summary view is not necessary and performance could therefore be improved by pre-rendering graph images.

Contribution by Group Members

	Ted	**Eddie**	**Jill**
Blackbox Management View	• File Management Class with iTunes File Sharing • *Create BlackBox* Popover Interface • Grid View Interface	▨	• Initial design and concept
Main View	• Video manager class • Video playback controllers • Toolbar manager class • Toolbar popover design implementation	• Toolbar graphic design • Toolbar popover design • Numeric data collector (reading CSV data) • Vital sign manager class • Graph generation view controllers • Graph alert generation • Body temperature and NBP display	• Initial design and concept • Toolbar content (selected frequently used evaluation checklists) and popover design • Simulated vital sign data using MatLab
Summary View	• Annotation timeline generation • Annotation legend popovers • Annotation CSV export to iTunes tool	• Final interface design • Vital sign graph generation • Annotation timeline generation and popovers	• Initial design and concept
Testing and feedback	▨	▨	• Distribution of user-friendliness questionnaires to health care providers • Tested app with surgeons at St. Michael's Hospital

Apper Context

The OR blackbox is a useful evaluation tool in the field of surgical education that provides a complete documentation of all events that occur during a surgical procedure. The app allows the user to view multiple feeds from the OR and evaluate surgical skills using the evaluation forms featured on the toolbar. By reviewing surgical procedures on the OR blackbox, we will be able to:

- simultaneously evaluate technical skills (e.g., manual dexterity) and non-technical skills (i.e., teamwork, communication, leadership) of the surgical team;
- study the multiple factors that contribute to an error in the OR;
- determine the pattern of events that lead up to adverse outcomes in the OR;
- identify the key steps of surgery that are statistically correlated to errors, which can then be simulated in a scenario-based surgical curriculum.

Ultimately, the OR blackbox has the potential to reduce the rate of error in the operative environment, thus improving patient safety.

Testing of the App

We tested the usability of the app with two surgeons at St. Michael's Hospital. Both surgeons evaluated a 10-minute clip of a gastric bypass procedure using the error rating tool found on the toolbar of our app. Technical errors detected in the video clip were tagged, and the time-stamped data was then exported to statistical analysis software to measure the inter-rater reliability between the two raters. Inter-rater reliability measures the degree of agreement (i.e., homogeneity) between two ratings given by surgeons. We applied a statistical test (Cohen's Kappa) onto our data in Excel, which generated a kappa-coefficient (κ) of 0.8. This value indicates that there is a significant degree of agreement between the two ratings, suggesting that the error rating of both surgeons accurately reflects the technical errors in the video clip.

At the end of the testing phase, both surgeons agreed that the app is an effective tool for evaluating surgeries. It was also agreed that the app is more efficient and user-friendly than the conventional method of rating errors, which involves writing down the time at which each error occurred on paper.

Future Work

After testing the app with surgeons at St. Michael's Hospital, we have shown that the current version of our app is functional for the "clinical user". However, there are several improvements that we can work on:

- **Accessing blackbox data from a server**: Blackbox data could be hosted on a server and streamed directly to the app on the iPad. Using a server, we would no longer need a manual file management system in iTunes. Confidentiality would be maintained by using several layers of authentication as well as requiring network communications to run over an encrypted virtual private network (VPN).

- **Live observation of a surgical procedure** can provide members of the surgical team with immediate feedback on their performance. By signing onto the blackbox server, video and vital sign data could be streamed directly from the OR equipment to the iPad app via VPN. However, we must first find a seamless way to extract data from OR equipment in real-time.

- Based on feedback from the surgeons at St. Michael's Hospital, the user experience of our app can be enhanced by creating a **customizable layout for the main screen**. The user could re-arrange and re-size the video and vital sign feeds for optimal viewing.

- **Plain text annotation feature** would allow the user to write notes in freeform without conforming to a particular checklist.

References

1. Baker GR, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ*. 2004; 170:1678-1686.

2. Guerlain S, et al. Assessing Team Performance in the Operating Room: development and use of a "black-box" recorder and other tools for the intraoperative envrionment. *J Am Coll Surg*. 2005;29-37.