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Design of an X-Ray / Ventilator Synchronization System in an Integrated Clinical Environment

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Abstract—**Patients in an ICU may receive daily chest x-rays. These x-rays are taken manually and may be at different phases of respiration, which limits their clinical usefulness. We examine design issues around automatically synchronizing an x-ray and ventilator in an interoperable manner, including requirements on the individual devices and new safety hazards introduced by connecting them into a system.**

I. Background

Patients in the Intensive Care Unit frequently have their breathing assisted by a mechanical ventilator. These patients typically have a chest x-ray performed on a daily basis to guide clinical decisions regarding antibiotic, and diuretic therapy, or the position of the breathing tube. Several studies have recommended daily portable Chest X-Rays (CXR) in these patients to evaluate the position of endotracheal, orogastric, or nasogastric tubes, and changes in pulmonary infiltrates or acute lung injury [1-4].

For the X-ray images to have optimal diagnostic value, conditions must be the same for each exposure. This includes factors such as the focal distance from the X-ray machine to the patient's chest, the amount of energy used, and exposure time. The most important factor affecting film quality is the degree of lung inflation at the instant the film is exposed [5]. Changes in lung volume and pressure during mechanical ventilation are known to substantially alter the appearance of the bedside CXR. Since the ventilator runs continuously, the X-ray technician must currently use visual cues to manually trigger the X-ray at full inflation. The degree of inflation and the pressure in the lung at the instant the CXR is taken is entirely dependent on when the radiographer triggers the machine to acquire the CXR. Manually exposing the radiograph film at the exact peak of inflation may be quite difficult because the inspiratory pause may be brief, especially in seriously ill patients who require complex ventilatory modes, or in pediatric patients who typically receive rapid respiratory rates and small tidal volumes.

The result is CXRs obtained at sub-maximal inflation that do not provide optimal diagnostic information. Films taken at less than full inflation are often misinterpreted as demonstrating increased lung water due to crowding of vasculature [6]. Chest radiographs of variable quality may lead to additional film acquisitions. Patients are then exposed to extra radiation when repeated x-rays are necessary.

Previous studies have shown that automatic synchronization leads to significant changes in image quality and consistency, but these systems have been one off custom solution built for a study, and therefore have not been commercially available. The goal of this project is to prototype an application that utilizes standards based communication and a "safety system architecture" methods to synchronize the acquisition of x-ray images with the desired phase of ventilation to acquire consistent lung images and improve the safety and efficacy of chest x-ray. This will be done with a standards based approach using the functional architecture of the ASTM F2761-09 Standard.

The work presented here is an extension to earlier work by the MD PnP program [5]. That system demonstrated that automatic synchronization with one mode of an anesthesia machine in a surgical setting was possible. This paper builds on that work by supporting multiple modes of a standard ventilator, including some spontaneous breathing, and doing so in a more open and interoperable manner. We examined three models of ventilators for suitability, worked with clinicians to analyze the clinical workflow around daily chest x-rays, designed a system to support that workflow, and performed a hazard analysis of the composed system. This work will support clinical trials of an x-ray synchronization system planned for the near future.

II. Methodology

Requirements for the system were gathered by meeting with clinical and technical domain experts to document the current workflow for daily chest x-rays. Figure 1 shows the workflow together with our system. A systems level risk analysis was completed. Techniques for mitigation of these

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risks became nonfunctional requirements for the system.

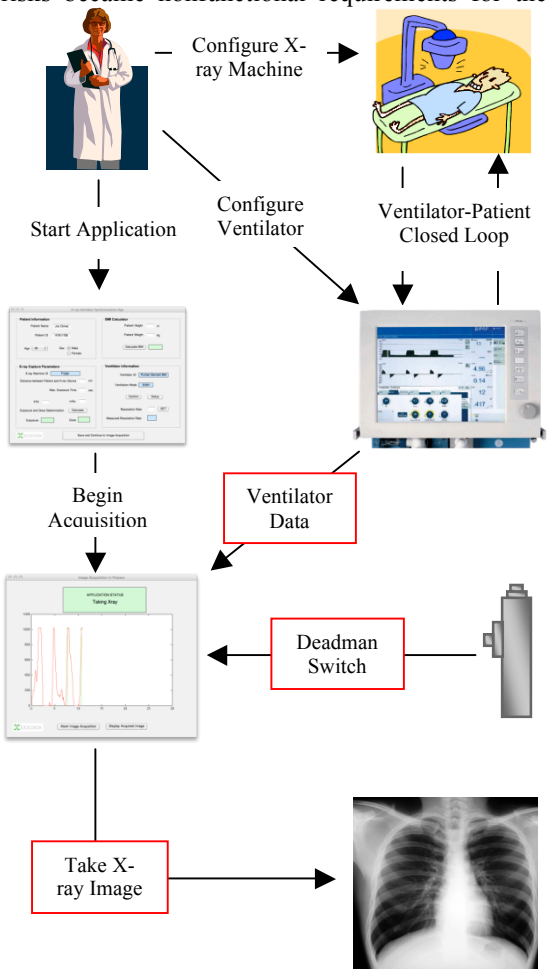

Figure 1: X-ray ventilator synchronization workflow

A. *Ventilator Modes*

Clinicians we consulted were most interested in synchronizing with the ventilator modes of Assist Control (AC) and Synchronized Intermittent Mandatory Ventilation (SIMV), so these two modes are supported in this study.

In AC mode, the ventilator delivers a fixed number of breaths per minute to the patient, who is typically sedated, unconscious, and completely unable to breathe for himself. It is thus relatively easy to synchronize with the patient's breathing, as it is entirely machine controlled and predictable provided that no settings are changed or alarms occur. The system in [5] worked only in AC model.

SIMV mode is used with patients who are breathing spontaneously, but not marinating adequate respiration. In this mode, the ventilator is set to provide a number of breaths per minute, e.g. on a 5 second cycle. If the patient initiates a breath in a cycle, the ventilator provides pressure to assist the breath. Otherwise, the ventilator forces a breath at the end of each cycle. The patient may take additional breaths on their own. Thus, patients in SIMV mode are much more mobile than those in AC mode, and synchronization is more difficult. A particular challenge is the possibility of patients coughing, which can cause intense pressure spikes.

B. *Algorithm Design*

Clinical requirements state that an acceptable X-ray can be taken when the patient's lungs are at between 90% and 100% of the full inspiration pressure. The system must also determine if there is enough time within the 90%-100% window to deliver the necessary x-ray exposure. This is illustrated in Figure 2.

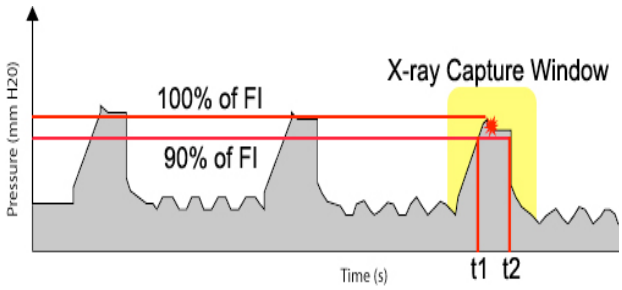

Figure 2: The X-ray capture window

We use settings data from the ventilator together with real-time pressure and flow data in order to detect the peaks in the respiratory cycle and correctly trigger the x-ray.

We tested the algorithm using recorded data from actual patients gathered from the PhysioNet database, and by manually creating test scenarios using lung simulators in the MD PnP lab. The lung simulators allowed us to create coughs and other irregular breathing patterns typical of those encountered with patients connected to a ventilator in the SIMV mode.

This initial simulation and testing work will be greatly expanded when we start capturing real patient data during the initial phase of the clinical trial described below.

We collected data from three models of ventilators: the Dräger Evita XL, and two versions of the Puritan-Bennet 840: the 10.3 and 10.4. The Evita XL and 10.4 version PB 840 provide pressure and flow data at a rapid enough rate (50Hz for the PB) to support our algorithm, while the 10.3 version PB 840 can only provide this data on a cycle of about 800 mS, which is too slow to support synchronization.

C. *System Actors and Roles*

The **X-ray technician** is the user of the system. Prior to using the X-ray Ventilator Synchronization Application, the X-ray Technician is required to configure the X-ray Machine and the Ventilator. Once the X-ray Machine and Ventilator have been configured, the technician can initiate the application. The **X-ray Ventilator Synchronization Application** acquires pressure, volume and flow data from the Ventilator using serial communications and analyzes that data to determine when the patient is at full inspiration. Once the window of full inspiration is determined, the application

triggers the X-ray machine to take an image at full inspiration.

The **User Interface** has been designed as a sequence of windows guiding the user through the process of acquiring a synchronized X-ray Image. The developed UI consists of four core windows: Login, System Initialization, Image Acquisition and Image Display.

The Login Window authenticates the user and grants access to the application. Upon successful authentication of the user, the System Initialization window allows the user to document information about the patient, perform BMI, Exposure and Dose Calculations and document parameters for X-ray Image Capture. The information obtained by the underlying algorithm from the ventilator (for instance the ventilator ID and ventilation mode) is displayed to the user for confirmation. Once all the necessary information has been provided or confirmed by the user, the user can save the information and continue to the Application Initialization Window shown in Figure 3.

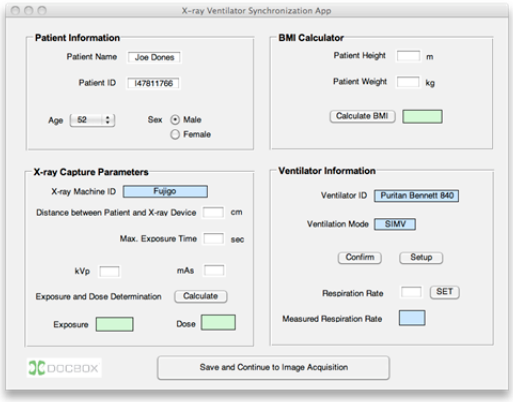

Figure 3: The Application Initialization UI

The Image Acquisition window, Figure 4, displays the Pressure or Volume Waveform being used for peak detection and subsequent image acquisition. It also displays real-time status messages of the application. It gives the user the capability to abort image acquisition at any time during the process. Once the image has been acquired the user can view the acquired image by clicking the "Display Acquired Image" button in this window.

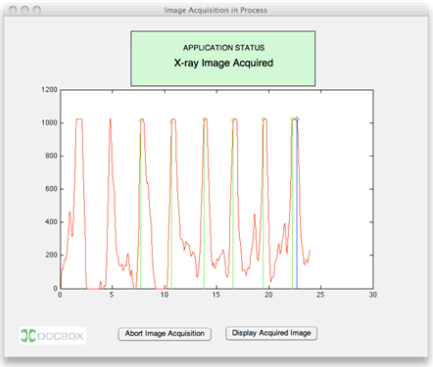

Figure 4: The Image Acquisition UI.

The **dead-man switch** is an additional safety mechanism used to prevent unintentional triggering of the x-ray. The X-ray technician holds down the switch to give the algorithm permission to trigger the X-ray machine. By releasing the switch, the X-ray technician can abort the application, in turn, stopping the X-ray machine from exposing the patient to X-ray radiation.

III. Hazard Analysis

One difficulty seen in developing interoperable medical device systems is mitigating new hazards brought on by the combination of multiple devices. A system-level hazard analysis is a key aspect of the design that allows for non-functional requirements to be designed into the systems. It also supports validation and verification of the individual devices as well as the system as a whole. Hazard analyses for individual devices are done as part of the development process for those devices. However, when devices are combined in new ways, new hazards are introduced. We documented many of these hazards, their probability and likelihood of harming the patient, and their mitigation strategies. A few sample hazards and mitigations can be seen in Table 1. The full table contains 137 hazards.

Hazard	Risk	Mitigation
X-ray machine overexposes patient and/or operator	Occasional Moderate Medium Risk	Design system to work with a dead-man switch to avoid unintentional X-ray exposure.
Failure to abort X-ray during Emergency	Probable Moderate Medium Risk	Training of X-ray to abort image acquisition in emergency. UI Assistance for the same.
Multiple trigger requests leads to excess radiation exposure.	Frequent Major High Risk	System Timer of 30 s aborts application after timer expires to avoid repeat triggering.
Failure to initiate trigger	Frequent Minor Medium Risk	Clear obstruction from screen, clean screen. Application UI must be checked. Algorithm will abort after 30s.
Unauthorized person removes or tampers with mechanical X-ray trigger assembly.	Occasional Major Medium Risk	Physically lock the assembly. Require lock to be closed before starting application. Alarm if application is run with switch unlocked.

Our interoperable system relies on consistent communication with the ventilator. While we initially focused on communicating real-time respiratory data (pressure, volume, volumetric flow, etc.), it was also important to communicate any alarms from the devices. We first listed the device alarms that could be translated across the device's serial communication port. Then the algorithm was adapted to analyze any incoming error message and decide if it was safe to continue despite the alarm, or if the

application should stop. In either case, a message informs the user of the alarm.

In addition to discovering the hazards associated with the ventilator, hazards related to X-Ray machines and imaging were also studied. Excess radiation exposure was the main hazard that we attempted to mitigate. Patients, caregivers, technician, and passersby are all susceptible to radiation exposure. The dead-man switch as the main mechanism we employed to mitigate these hazards. Other hazards such as power loss, unresponsive exposure dials, and cathode disconnection are present in x-ray machines, but excess exposure is the main hazard affecting patient safety.

Our interoperable system communicates electronically with the ventilator, but no current x-ray machines have suitable interfaces. Instead, we plan to trigger an x-ray image by activating the mechanical switch used to take an image.

There are three main areas where our interoperable system introduces new hazards. They involve ventilator communications, the algorithm triggering the switch, and taking the x-ray image. For example, the ventilator communications could potentially cause the synchronization application to enter a holding state not allowing any image to be triggered.

Additionally, the algorithm may not be able to find an appropriate spot in the respiratory cycle to trigger the x-ray, preventing a necessary x-ray from being taken. This risk is mitigated by a 30 second timer introduced into the algorithm. In the clinical trial, we will have a manual override option in case the x-ray technician decides that the system is not working properly. Another timer enforces a minimum time interval between exposures to prevent multiple rapid triggers from causing an excessive number of exposures.

IV. Future Work and Clinical Testing

Clinical testing will take place in the Medical Intensive Care Unit (MICU) at VA Boston. We will test several ventilatory modes, including AC and SIMV. We will evaluate efficacy by comparing the quality of full inflation positive films with the quality of full inflation negative films. In addition, we will compare the quality of full inflation positive films with that of full inflation negative films obtained on the same patient on two consecutive days. IRB approval will be obtained prior to human testing.

The first phase of testing will simply capture data from the ventilator and tag it with the time when the x-ray is manually triggered by an x-ray technician. This data will be used to refine and further test the synchronization algorithm.

Board-certified radiologists will assess the quality of films taken by the algorithm using a point system based on variables particular to chest films, including number of ribs and diaphragmatic curvature to estimate chest inflation, density of lung markings, and clarity of the mediastinum. Other parameters recorded will include beam energy, distance from the X-ray machine to the patient, and lung volume and peak pressure at the time of film exposure, as well as a measure of patient size (BMI). Regression analysis will be performed on the collected data using Quality as the dependent variable and the parameters above as independent variables. Further, we will record the clinical decisions that were made based on synchronized versus unsynchronized films.

V. Conclusion

The aim of this study is to demonstrate the efficacy of synchronizing x-ray images with respiratory wave forms for mechanically ventilated patients, especially those who may breathe spontaneously. After successful clinical trials, we will then generate standards for interoperability interfaces. These interfaces can be used with portable X-ray machines and ventilators that are generally available and can be implemented by manufacturers of these devices in the future.

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