Evaluation of a Long-Term Continuous Full Disclosure Archiving System for Multi-Parameter Patient Monitoring Devices

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Abstract

This paper evaluates the design and implementation of a long-term full disclosure archiving system for use in patient monitoring settings. The eData TapeRec system continuously collects and stores waveforms, parameters and monitoring alarms from the patient monitors in the intensive care cardiology unit, intensive care thoracic surgery unit, the medium care units and operating rooms of the Erasmus MC. The recorded data can be archived to offline storage media (CD/DVD) and exported to open file formats, such as MIT/Physionet. The eData TapeRec system is in use since 2004 at the Erasmus MC and in other institutes.

1. Introduction

Patients admitted to intensive care units, (cardiothoracic) operating rooms and step down units are closely monitored 24 hours a day by either multi-parameter patient monitors or by multi-lead telemetry devices. Although most commercial patient monitoring vendors provide dedicated workstations which store waveforms and events for up to 72 hours, this data will be lost after that period unless a clinician prints out the events or episodes of interest in order to prevent permanent data loss.

The Erasmus MC has developed the eData TapeRec system which continuously collects and stores waveforms, trend parameters and monitoring alarms from the online patient monitors in the intensive care cardiology unit (8 beds), intensive care thoracic surgery unit (10 beds), medium care units (3 units of 16 transmitters) and operating rooms (4 induction and 4 OR). The eData TapeRec system is the second generation of "tape recorders" in use at the Thoraxcenter since the 1980s. The first generation tape recorders [1] were installed at the cardiothoracic surgery department. For each operation data was recorded on electromagnetic tapes that were manually started before and stopped after each procedure.

In this paper we provide a description and an evaluation of the eData TapeRec system in use at the Thoraxcenter.

2. System overview

The overall requirements for the eData TapeRec system were to provide a data collection and reviewing system with an archiving option to offline storage (CD, DVD, SAN) and to accommodate (clinical) research. The system should be able to store at least 168 hours (1 week) of data per patient and should process patient admissions and discharges automatically without human intervention. To prevent disk capacity problems, the system should provide automatic archiving of older recordings.

For research purposes, it should be possible save recordings to external storage such as CD or DVD and extract or export data to open file formats, such as Matlab, text files and the MIT/Physionet file format [2].

2.1. System architecture

All patient monitoring devices installed at the Thoraxcenter are connected to a dedicated patient monitoring network which is separate from the hospital network. Figure 1 provides a list of devices which includes (portable) patient monitors, nurse stations, recorders, patient data management systems and IT connectivity systems such as the Infinity Gateway device [3]. This Gateway device provides web-based viewing of bedside data, but also provides an API to access vital signs, waveforms, and alarms.

The eData TapeRec system uses the API to obtain the list of admitted patients and to collect the vital signs, waveforms and alarms from the patient monitors and attached devices such as ventilators. For patient safety and modularity, eData TapeRec does not connect directly to the patient monitoring devices, but uses the Gateway as a proxy device to make connections on its behalf.

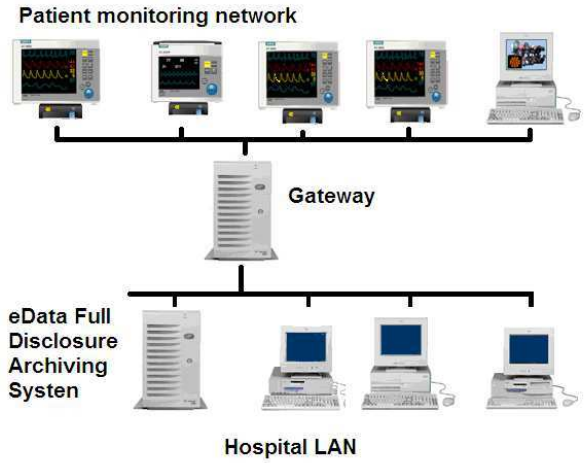

Figure 1. Installation of eData TapeRec with the links to the patient monitoring network and the hospital network.

TapeRec uses files to store patient data received from the Gateway. The smallest storage unit of TapeRec is a slot which stores patient-related data in a file with a fixed size. For the online beds, the file slots are pre-allocated on the storage disk in order to avoid unnecessary fragmentation and increased disk seek, read and write times during the continuous 24x7 operation of the system.

Each file slot uses a round-robin allocation scheme and is divided into equally-sized parts. New data replaces the oldest data. The round-robin allocation of TapeRec provides $O(logN)$ retrieval and storage costs. For further optimization, TapeRec uses a separate index file for each slot to optimize positioning in each slot. The main reason for this is that the timestamps of the stored data packages may not be contiguous. For example, if the patient monitor is disconnected, TapeRec temporarily stops writing to the files instead of writing blank data.

The Gateway API provides TapeRec with information when a patient is admitted, a bed is discharged, or patient information is relabelled. TapeRec also tracks if a patient monitor has been moved to a different IP address (e.g. from the operating room to recovery) and automatically appends the data from the new information to the right slot.

In addition to a file with a list of slot information (including current status, patient demographics), eData TapeRec maintains a number of other files for each logical slot. Table 1 provides an overview of these files. Data in these files remain in the proprietary format that is supplied by the Gateway.

At each point in time, TapeRec allows exact reconstruction of the patient monitoring screen based on the information in the files. This makes it possible to look up, isolate, store and inspect data *post hoc* for new patterns that may explain the event or for forensic and archival purposes.

Table 1. Data acquired and stored by the eData TapeRec system.

File Type	Data Type
Waveforms	ECG, ART, LA, RA, SPO_2, etc.
Trends	1-minute trends of vital signs (up to 129 parameters, including HR, NIBP sys/dias/mean, etc.
Complexes	Averaged ECG complexes (1.2 s)
Device Settings	Display layout, device alarm settings, patient demographics
Events and Alarms	Patient monitoring alarms (grade, state, time), manually marked events, annotations, messages displayed on the monitor.

The TapeRec system only uses file system input/output and uses single writer/multiple reader locks for the files. Most files are in a binary format, except for the patient demographics and event annotations.

2.2. Access to patient data

TapeRec provides a storage API for applications which consume the information in these files. Figure 2 provides an overview of the storage API and the programs that use the API to access the patient data. These applications include review, annotation and export possibilities. The API provides location and storage transparency to the application and user. The web-based and file-based input/output modules are implemented in a Microsoft Visual C++ class library with extensions to Microsoft Internet Information Services web server for transport over HTTP.

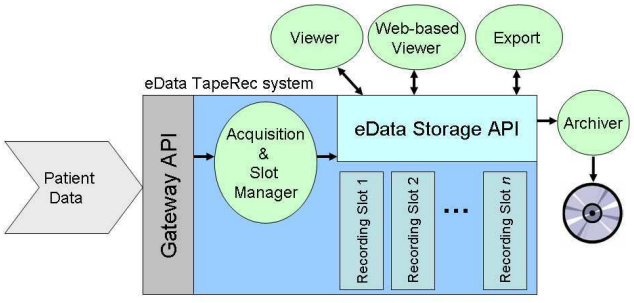

Figure 2. Overview of the TapeRec processes, the storage API and the external programs that use the API to access patient data.

2.3. Active and archive list

The TapeRec system manages a list of active and archived patients. The list of active patients includes all records of patients that are currently admitted and connected to a patient monitoring device.

The archive list contains the recordings from patients that were discharged. When patient monitoring is discontinued (discharge), recordings from the active list are transferred to the archive list after a user configurable timeout (by default 8 hours). The timeout avoids prematurely transferring data to the archive list for patients that are temporarily disconnected, due to, for example, a diagnostic test at a different department.

2.4. Review and annotations

The eData TapeRec system contains Clinical Review Software (CRS) that provides a basic reviewing and annotation graphical user interface. Figure 3 shows an example of the waveform screen of CRS. The CRS is a modified version of our earlier work [4] and uses the storage API. CRS is component-based system which can be used as a standalone viewer, a dedicated viewer on the TapeRec server and an ActiveX control on a webserver.

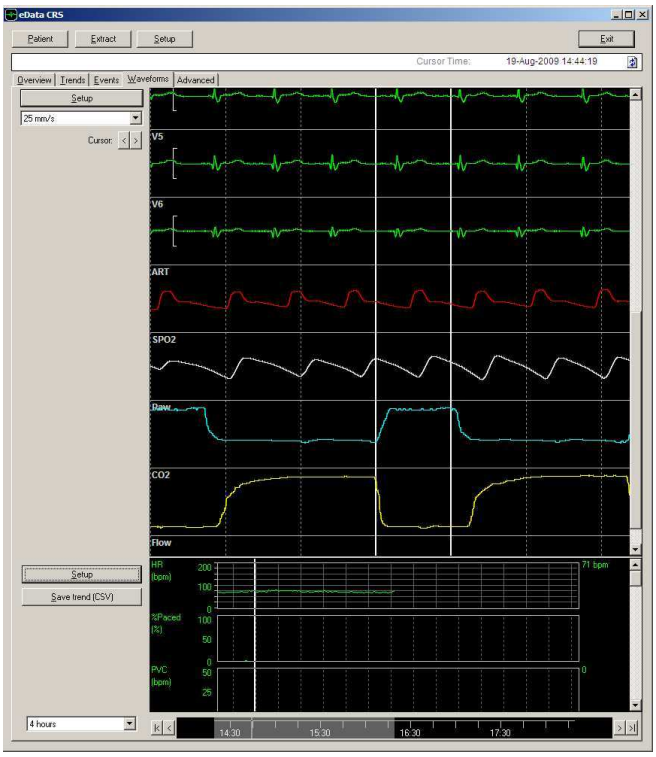

Figure 3. Full disclosure screen of the eData Clinical Review Software that can be used for both online and offline reviewing and annotating patient data.

2.5. Export

The eData TapeRec system provides several export interfaces, including: comma-separated text files (CSV) for trends and waveform snapshots, Matlab (waveforms), European Data Format (waveforms) [5], and MIT Physionet files (waveforms) [2]. Events and annotations can be exported as text or XML.

3. Results

With the eData TapeRec system we can review, store and archive all data collected by our patient monitoring devices which allows us to store and archive patient information electronically instead of only being able to print out certain specific events and or strips before the data are deleted.

The system was made available to researchers and high-end users of our institute in 2004 and over the years to 5 other (clinical) research medical centers. The tool opened many opportunities to capture full disclosure data as part of clinical evaluations and studies with the ability to export parts of these waveforms for reanalysis.

Apart from its primary goal, the system is also used for forensic and archival purposes. In the operating room, the medical OR documentation can be supplemented with the complete full disclosure patient monitoring record as archived by eData TapeRec.

4. Discussion and conclusions

Continuous long-term (ECG) monitoring systems have been in use since the introduction of intensive and coronary care units [6] in the 1960s for hospitalized patients and patients at home [7]. Several research systems have been proposed to store these vast amounts of data [8, 9, 10] in addition to the commercially available full disclosure systems, which generally lack long-term storage (more than 72 hours) and export facilities with open formats. TapeRec is a system that combines and extends the functionalities of these research and commercial systems. First, the tool can be used for online (clinical) data collection and research without interfering with clinical care and workflow. Second, complete TapeRec files can be saved, exported and archived to open and standard formats.

An important consideration of the design is that TapeRec stores patient monitoring data in files only. Although a file storage strategy is flexible (new data types can be added easily in new files) and does not require external software (e.g. database management systems), data access and data integrity are issues that needed to be addressed. Because TapeRec is a single-writer, multiple-reader system, data access and integrity can be controlled by using the facilities of the file system. Obviously, a database management system (DBMS) can be used to address these issues as well and

may provide simultaneous data access and standard storage. However, a SQL-based database system may not be the best solution for the type of data which is often strongly related to patient and time. A hybrid approach (files and with relational database for most textual data) or an object-oriented DBMS may be a better fit.

A major limitation of the eData TapeRec system is that it is designed to work with a specific patient monitoring device manufacturer. The system is interfaced with a gateway system using an API that has been also specifically designed for receiving data from devices connected to the gateway system. Other medical device manufacturers provide similar systems and also provide specific APIs. To make TapeRec independent of manufacturer-specific communication protocols, the TapeRec acquisition modules could be enabled to use the IHE communication profiles [11]. In recent years, IHE has provided profiles for standardized communication of vital signs, alarms and waveforms (in progress), but these profiles are not yet fully implemented by manufacturers or are not completely defined and approved yet.

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