Software Requirements Specification

for

Thousand Smiles Digital X-Rays

Version 1.0

Prepared by Syd Logan

Thousand Smiles Foundation

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Revision History

Name	Date	Reason For Changes	Version
Syd Logan	03/20/2016	Original	0.9 Draft
Syd Logan	04/18/2016	Add requirement for chair-side portable x-rays	1.0

1. Introduction

1.1 Purpose

The purpose of this document is to outline the basic requirements associated with the Thousand Smiles Digital X-Ray functionality.

1.2 Document Conventions

There are no specific conventions associated with this document.

1.3 Intended Audience and Reading Suggestions

The intended audience includes:

Thousand Smiles Board Members: Board members should read this document to become familiar with the overall overall scope of the digital x-ray project. This knowledge may prove helpful as background when evaluating logistics and expenditures associated with the implementation of the system, e.g., equipment purchases.

Design Team: The user experience design for the system is based on the requirements defined in this document.

Implementation Team: This document spells out requirements which guide the implementation of the system. It is not intended to be a design document, rather it spells out the requirements that a design must follow to be considered valid.

Users: This document must be read and approved by the end user(s) of the system. This document will likely go through some number of revisions towards eventual approval. If asked to review, comment on, or approve this document, please read the document critically and identify any omissions, errors, and changes so that they can be dealt with.

1.4 Product Scope

The following sections briefly summarize the scope of the system. Detailed requirements for each will be presented later in this document.

1.4.1 Digital X-Rays

Since its founding, Thousand Smiles has made use of traditional, non-digital x-rays in their clinics. The basic process is as follows: a patient is identified as needing x-rays, x-rays are taken of the patient and developed, and the resulting films are placed in the patient chart (or otherwise delivered) for use by dentists and orthodontists at the clinic. These films are kept as a permanent part of the patient record for use in subsequent clinics if desired.

Thousand Smiles has recently received a generous donation of two (2) Gendex DenOptix digital films scanners. These scanners, attached to a Windows-based PC via USB cable, provide us with an opportunity to scan the film x-rays and deliver digital x-rays to end users. They also provide us with an opportunity to improve how we store and access patient x-rays.

The requirements in this document do not address the process by which a dentist or orthodontist requests x-rays for a patient, or the process used by a radiologist to obtain and process the film-based x-ray. Nor does it discuss how the film-based x-ray is converted to a digital form. It does discuss how the digital x-ray is stored, once scanned, into a database (the patient digital chart), and how the resulting image can located and viewed by dentists and orthodontists.

2. Example Patient Scenario

Patients coming into the system are registered in our digital chart system (for details, see **Thousand Smiles Digital Charts Patient Registration and Routing, Version 1.2 (3/20/2016)**).

Patients are routed by the above system to a dental or orthodontic chair. X-rays are ordered, and this is communicated to radiology (possibly by adding x-ray to the routing slip of the patient when the patient enters the system). The ordering of x-rays might be done automatically because the patient is identified as dental only, or because the routing slip of a cleft patient has been marked as needing dental (and/or x-rays) at some point, or possibly because the dentist determines that x-rays are needed while the patient is in the chair.

Regardless of when the need was determined, the patient will eventually be routed to radiology where x-rays will be taken. The films are developed and then scanned by the DenOptix devices. The radiologist will save these images to disk along with metadata (patient ID, type of x-ray taken, etc..) that identifies the x-ray. The metadata of the image, along with a pathname to the actual image, is stored in a database.

At some later time, the patient is routed to a dental or orthodontic chair. The medical personnel are given the name, DOB, and ID of the patient. The personnel use this information along with metadata and clinic date (current or past) to search the database for the corresponding digital x-ray(s). The medical personnel view the digital x-ray(s) on a tablet located at the chair.

A dentist or orthodontist may request image enhancements, or enhancements might be performed unsolicited by radiology at their discretion before the patient is routed to the chair. In either case, a dedicated workstation equipped with GIMP (preferable due to being no cost) or Photoshop can be used to perform the needed enhancements. Alternately, easy to use image viewing software (third party, or possibly software we develop) might be used by a dentist or orthodontist to provide basic enhancements (e.g., contrast, brightness, zoom, histogram equalization) at the chair. The scope of such software would be limited to simple operations, nothing like what might be provided by software such as GIMP or Photoshop.

2.1 Portable X-Ray Devices at the Dental Chair

The system should support the use of portable x-ray devices at the dental chair. The images that are collected by a portable device must be uploaded into the database in the same manner as images taken away from the chair. Care needs to be taken to ensure that the process does not negatively impact the workflow of the dentist.

3. Requirement Details

3.1 Registration

As was mentioned above, Thousand Smiles is currently in the process of designing a digital chart replacement, and registration of patients falls into the scope of this new system. However, in order to get digital x-rays into use at our clinics as soon as possible, we will design and implement a very basic system needed for registering those patients which are in need of digital x-rays. The requirements for this system are roughly a subset of those defined for the mainstream digital charts, providing just enough functionality to allow us to identify patients and find their x-rays. Paper charts currently in use at the clinic will still be used as is; the registration described here will be added to the current process.

3.1.1 Basic Patient Information

Basic information includes name, gender, DOB.

- Patient ID (generated by the system, unique for each patient)
- Patient name (father last, mother last, middle, first)
- Patient gender
- Patient date of birth

3.1.2 Medical History

No medical history will be taken at this point for patients.

3.1.3 Headshot

No headshot will be taken at this point for patients.

3.1.4 Category

Patients fall into one of several categories:

- Dental-only patients. These patients are typically new patients that do not have cleft, and require general dental services such as fillings and extractions.
- New cleft patients. Often infant, but possibly older. These patients are candidates for surgery screening, ENT, Audiology, and speech. Depending on the screening and medical history, they may have surgeries performed on the second day of the clinic. These patients will not have any data in the system, will not appear in search results.
- Returning cleft patients, non-orthodontics. These patients have been seen at a prior clinic and were asked to return for follow-up care that is not related to orthodontics. Such care might include additional surgeries, or delivery and application of a hearing aid, etc.
- Return cleft patients, orthodontics. These patients have been seen at a prior clinic and were asked to return for orthodontic care.
- Unknown. The patient does not fall into any of the above categories, or the correct category is not evident to personnel at registration. In response, registration personnel have decided to not turn away the patient. The patient is similar to a new cleft patient but the category of unknown alerts personnel to the fact that the situation is not clear.

3.2 Process for Registering Patients

When the patient is identified as needing x-rays, he or she will be registered as such in the database. The basic steps include:

1. Searching for the patient in the database.
2. If the patient is not in the database, add a new record for the patient, or
3. If the patient is already in the database, update his or her information
4. Record the date of the clinic visit

3.2.1 Searching for a patient at time of registration

The first step in the process of registration involves searching the system for the patient. This step is critical for two reasons:

1. Failing to find an existing patient will consume addition time needed to re-enter patient data that is already present in the database, thus slowing the overall process of registering patients for the clinic
2. if an existing patient is not found in a search and is registered as a new patient, this will result in a duplicate record in the database for that patient. This duplicate will not be linked to any data that was gathered for the patient at earlier clinics, including (but not limited to):

    - Surgery history
    - Return to clinic instructions
    - Clinical photos, x-rays, etc..

Thus, it is important for the search function to be accurate and easy to use.

The system must provide a search screen that accepts the minimum amount of data required (last and first name, gender, date of birth, etc..) to enable the system to search for and identify patients in the database. The volunteer will enter as much data as needed to accurately search the database. Generally, the less data that is entered as search parameters, the more patients that will be returned by the search. Example: if only the gender is entered, then all patients matching that gender will be returned in the search results. Generally, the system should favor searches based on the patient providing a patient ID. Failing that, last name, first name, gender, and date of birth are good search parameters for the system to support.

If the search yields positive results, the volunteer should be able to choose from one of two methods to view these results. The first method is a list of names, gender, date of birth, last clinic visit date for the patients that match. Each result should include a headshot as a thumbnail. Clicking on the thumbnail would enlarge the headshot to aid in viewing. Alternately, the system should display a list of headshots for all of the matching patients. Clicking or selecting a headshot will display the name, gender, data of birth, and last clinic visit date for the selected headshot. The volunteer should be able to choose which method is appropriate for the situation, and should be able to toggle between the two. (Note, headshots are not in the scope of the x-ray system documented here, but will be a part of the main digital charting system being proposed).

3.2.2 Duplicates

The system shall employ a search heuristic that minimizes the chance of search misses due to mistyped search parameters. Possible ways to solve this are (but not limited to):

- use of SQL “LIKE” searches in the backend

- autocomplete: as the user types in characters, search results are queried in realtime and updated dynamically in the user interface. For example, when searching for a male patient, all males are displayed, when typing the letter 'A' associated with a male patient named "Alejandro", all males with first name starting with the letter 'A' will be displayed.
- Case-insensitive searches

3.2.3 Registering a new patient

New patients are patients that did not result in a match at search time. The search results screen must provide a button which is labeled "Add New Patient" should no matches be found. Clicking this button results in the display of the following screens, in order:

- Basic patient data – used to enter basic information about the patient
- Category – used to select one of the four possible categories

3.2.4 Register an existing patient

Should a search identify an existing patient, the same screens that were used for new patients are displayed in order to allow for updates. The screens will be pre-filled with information that was gathered for the patient the last time the patient was registered for the clinic. The system must require that a new headshot to be taken before registration is complete.

3.3 Scanning the X-Rays

The presumption is that a patient entering radiology has been registered for the clinic in the database.

The radiologist will be given the patient name, ID, DOB, etc. necessary to find the patient in the database. This will likely be on a paper chart. The radiologist will then search for the patient using this information. He or she will then upload digital x-rays for the patient using the provided software. The radiologist will complete a form that describes the metadata of the image for each image uploaded.

3.3.1 Image Metadata

Each image has the following metadata. This metadata is associated with the image at the time it is uploaded to the database:

- Patient ID
- Clinic date
- Timestamp of upload

This metadata will be used by the dentists and others in searching for x-ray images in the database.

3.4 Enhancing the Digital X-Rays

At times (maybe often), scanned images require enhancements. Such enhancements might include:

- Contrast adjustment
- Brightness adjustment
- Histogram Equalization

- Rescaling/Zooming/Cropping

All of these operations can be performed on an entire image, and at times, enhancements can be performed on regions of interest (ROIs) that are typically small rectangular sub-regions of an image. The need to perform such operations is determined by the quality of the image scan.

To perform these enhancements, software such as Adobe Photoshop or GIMP (a freely available, open source Photoshop-like program) are typically used.

Ideally, we will provide a workstation for such enhancements. The enhancements are performed after the image data is placed (along with metadata) into the patient database. Using some undetermined means, the operator of the workstation will be notified that an enhancement is needed. He or she will be provided:

- ID and name of patient
- Metadata used to identify the image (possibly an image ID)
- The nature of the enhancements

The operator will use the above to locate the image in the database, obtain the image data, perform and perform the enhancement. The resulting enhancement must be saved as a new image and added to the database, so that the original image is left unmodified.

3.5 Viewing the Digital X-Rays

X-Rays will be viewable at dental chairs using tablet computers. Initially, we will use tablet computers with the following attributes to determine feasibility:

- Diagonal size 10” or better
- Resolution 1280x800 or better

The Samsung Galaxy Tab 10.1 meets this criteria.

The operating system must be Android 4.4 or greater.

Near the dental area a wireless router will be used to provide connectivity to the database.

Dentists and Orthodontists will be given a paper chart for the patient when the patient arrives, and this will provide at a minimum the name and patient ID of the patient. There will also be some indication that the patient is in the database and has digital x-rays available for viewing

The dentist will use this information to search for the patient. The dentist will then be given an opportunity to search for x-rays for the patient based on clinic date and x-ray type, as desired. A list of images that match the search criteria, along with thumbnails of the located images will be displayed.

Selecting an image by name or thumbnail will cause imaging software running natively on the Android tablet to display the image. The following features should be supported by the image viewing software:

- Scale to screen (fit screen dimensions)
- Display Full Resolution
- Zoom (from full resolution only)
- Simple contrast enhancement and brightness/level modifications

The software is for viewing only – no modifications to the image data in the database can be performed by the dentist.

4. Network Design

4.1 Topology Overview

The network architecture of the system consists of the components depicted in the following figure:

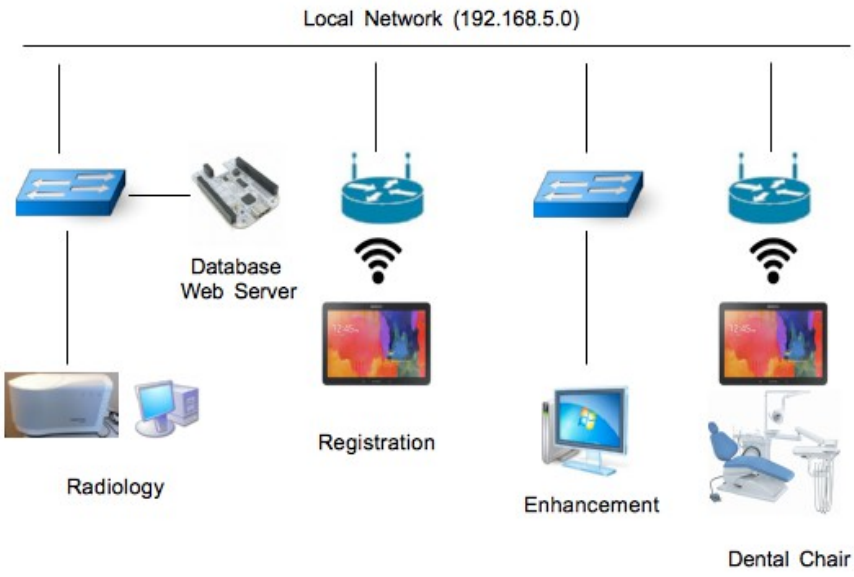

Figure 1 Topology

The various components are connected via an isolated private network. The use of a private network allows us to be isolated from traffic generated throughout the rest of the clinic, improving the speed, quality, and security of the resulting network traffic flow.

A single CAT-5 or equivalent backbone is to be run between radiology, registration, and dental areas. From this backbone, wired switches (1GB) will be located at radiology and enhancement stations. The database and web server will be located on the same wired segment.

Wireless routers will be placed close to registration and dental chairs. Tablet computers will be connected to these wireless routers. The passwords associated with the wireless routers will NOT be shared with volunteers to keep them from connecting to these devivces for Internet access.

The network itself will not be connected to the Internet except during off-clinic times when and only if maintenance is required. This will help ensure that patient data that flows through the network does not find its way out to the Internet, among other reasons related to security and efficiency.

5. Design and Implementation Constraints

Since we are providing the implementation for the system, there are no known constraints.

6. User Documentation

Documentation for the overall system, and the registration subsystem, shall be provided via YouTube videos and written documentation on the Thousand Smiles Wiki.

7. Assumptions and Dependencies

There are no specific assumptions or dependencies associated with the registration subsystem.

8. Other Requirements

No additional requirements have been identified for this subsystem as of now.

9. Appendices

Appendix A: To Be Determined List

<Collect a numbered list of the TBD (to be determined) references that remain in the SRS so they can be tracked to closure.>