Software Requirements Specification



for

Thousand Smiles Digital Charts – Audiology Subsystem

Version 0.9.2

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Revision History

Name	Date	Reason For Changes	Version
Syd Logan	12/18/2019	Original	0.9
Syd Logan	12/21/2019	Clarify that creation of Audiology data, and editing of previous audiology data, is only performed by an audiologist at the audiology station. Other users are only able to view the data, not create or modify it.	0.9.1
Syd Logan	12/27/2019	Add link to English translation of NOM to references	0.9.2

1. Introduction

1.1 Purpose

The purpose of this document is to outline the basic requirements associated with the Audiology Screening portion of the Thousand Smiles Digital Chart. This document focuses specifically on Audiology Screening requirements that were gathered via interviews with the primary stakeholders.

Audiologists work in collaboration with ENT, and surgeons, both which have separate portions of the digital chart dedicated to the data they record, and specified separately from this requirements document. Audiology records data for use by both Audiology and ENT directly, and others indirectly, towards the overall assessment of patients in the care of Thousand Smiles Foundation at our clinics.

The scope of this document is to describe the requirements related to the collection, storage, and viewing of audiology data stored in the digital chart system.

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 Audiology in the digital charts project. This knowledge may prove helpful as background when evaluating logistics and expenditures associated with the implementation of the system, e.g., equipment purchases.

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.

Audiology, ENT, Surgery Screening: This document must be read and approved by the end user(s) of the system, the audiologists, and should be read by ENT specialists, and surgeons who participate in our clinics. This document will likely go through some number of revisions towards eventual approval. Audiologists, ENT, and Surgery Screening should read this document critically and identify omissions, errors, and changes so that they can be dealt with.

1.4 Product Scope

The audiology screening portion of the digital chart is intended to provide the following capabilities:

- Ability to enter and save audiology data in the form of audiograms and free-form notes.
- Ability to refer to audiology data for a patient gathered at prior clinics.

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- Ability to view a medical history for the patient. A medical history is obtained at each clinic at the time the patient is registered.
- Eliminate the need for paper charts to the extent possible.

The benefits we hope to realize by supporting audiology data in our digital charts include:

- Increased access to data by other specialists. We aim to make the data recorded by audiology
 more easily located and viewed by other specialists involved with the care of the child
 during his or her visit at one of our clinics
- Increased reporting functionality. Migrating to a database-backed chart allows the organization to more readily generate reports; for example, number of children, types and numbers of procedures, incident counting (e.g., number of children seen with a specific condition). This data could be used for various purposes, both clinical and administrative in nature.

1.5 References

This document makes reference to the following documents

 Standard Official Mexicana NOM-024-SSA3-2010 <u>https://github.com/slogan621/tscharts/blob/master/docs/nom/NOM-024-SSA3-2012_English.pdf</u>

2. Chart Content

The audiology chart consists of the following components:

- Audiogram Facsimile
- Free-form text

Each of these components is available to Audiology, Surgery Screening, and ENT personnel when the patient has been checked in to the tablet at any of the corresponding stations. A component (e.g., Audiogram) can be selected from a menu available on the left hand portion of the tablet screen. When selected, an icon for each record of that component type (for that patient) which was created in the past will be displayed. Each will be labeled by the date that the record was created. Clicking on any one of these icons will result in display of the data.

In addition, a button will be displayed which, when pressed, will allow the users to create a new record of that type for the current clinic/date. This button will only be available at the Audiology station, other stations can view, but not create, new Audiology data.

For example, clicking the Audiogram icon will display a screen of all previous audiograms obtained for this patient, one per patient visit, labeled (and sorted) by date. In addition, a button that can be used to record a new audiogram corresponding to the current date is prominently displayed (Audiology station only).

The following subsections describe the data collected and displayed in each of the above listed components, as well as any specific requirements of each.

2.1 Audiogram Facsimile

The audiologist must be able to record and store one or more audiograms during the course of the examination.

The audiogram(s) are obtained using using specialized equipment and is rendered on a computer screen at the time of the examination.

This audiogram is currently printed out and placed in the patient paper chart.

In the digital records implementation, the tablet camera will be used to take a picture either of the screen or a printout of the audiogram, and the resulting facsimile/image will be stored in the database.

2.1.1 Operation

Selecting the audiogram button will result in a screen displaying icons that represent each of the previously captured audiogram images, ordered by most recent date.

Clicking on one of the icons will result in the screen displaying the corresponding audiogram.

A button will be available as the first icon on the screen, dedicated to creating a new audiogram. If this button is clicked, the tablet camera will be activated, allowing the audiologist to record an image of the audiogram (be it on a computer screen or a printout). If the user saves that image, it will be stored in the database, otherwise, it will be discarded.

2.2 Free-Form Notes

The audiologist must be able to record and store free form text notes during the course of the examination.

2.2.1 Operation

Selecting the Free-Form notes button will result in a screen displaying icons that represent each of the previously recorded free form notes for the patient, ordered by most recent date.

Clicking on one of the icons will result in the screen displaying the corresponding free form note.

A button will be available as the first icon on the screen, dedicated to creating a new free form note. If this button is clicked, a form will be displayed, allowing the audiologist to record and save the note. If the user saves the note, it will be stored in the database, otherwise, it will be discarded.

A previously edited free form note can be modified, but in doing so the free form note will retain the date of its first creation. Once created and saved, it is not expected that the free form note will be modified except to correct errors. Modification of these notes can only be performed at the audiology station. For all other stations, free form notes are read-only.

3. Other Nonfunctional Requirements

3.1 Performance Requirements

- The system should provide 99.9999% uptime during the clinic
- Search and access to the database should occur with a latency of no more than 5 seconds.

3.2 Safety Requirements

There are no specific safety requirements associated with this subsystem.

3.3 Security Requirements

We assume that the patient digital chart, and the audiology sub-system in particular, does not need to adhere to HIPAA requirements, and does not require HIPAA certification. Standard Official Mexicana NOM-024-SSA3-2010, which establishes the functional objectives and functions, must observe the products of Systems of Electronic Filing to ensure the interoperability, processing, interpretation, confidentiality, safety and use of standards and catalogues of the electronic records health information. An English translation of this standard is available, see References, above, for a link.

The system communication on the day of the clinic will occur locally and not leave the local network.

Users of the system will have accounts and must authenticate prior to using the digital chart. The user names and their passwords are unique to this system and are not the same used by the volunteer system; only a subset of our volunteers should be granted access to patient data. The database itself is physically and administratively separate from the volunteer database. Passwords will be encrypted on the system, and logging will be used to track account creation, login, and logoff activity.

3.4 Software Quality Attributes

There are no specific SQA attributes associated with this subsystem.

3.5 Business Rules

Access to the system during the clinic will be limited to authenticated users. There are no specific rules associated with who can authenticate.

Between clinics, database access will be restricted to the administrator of the system for purposes of backup and maintenance only. The patient data, and user account information, will not be accessible on the Internet except for purposes of backup and maintenance.

4. Other Requirements

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

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.>