Diasensor® 3000
Patient Data Processing Software Requirements

Contents

1. Introduction

1.1 Purpose

The purpose of this Software Requirements Specification (SRS) is to identify all the software requirements specified in the *Diasensor® 3000* Gamma Non-Invasive Glucose Monitor Design Requirements Document for processing User Data.

This document is to be used as a reference to identify all of the software requirements. For each requirement, the key system inputs and outputs are identified.

1.2 Scope

This document defines the requirements for the *Diasensor® 3000* Non-invasive Glucose Monitor, PDA Software

Software responsibilities:

1. The software is responsible for making *Diasensor® 3000* Calibrations and Re-Calibrations.
2. Software shall be designed to ensure the repeatability, reliability, and performance of the application or system according to its intended use.
3. The software shall generate weekly reports. & event Driven Reports
4. The software shall produce Glucose Measurements and averages.

The requirements listed above are described later in this document. 5.2 Runs in C compact code & interfaced w/SQL DB

1.3 Definitions, Acronyms, and Abbreviations

Calibration - The collection of Calibration Data and the processing of the data to extract a User's Calibration Coefficients. The Calibration process does not include Glucose Measurement.

Calibration Coefficients - A set of coefficients used by the Measurement Algorithm when calculating a Glucose Measurement. The coefficients are extracted from Calibration Data that is collected from a User for a single *Diasensor® 3000*. This results in a unique set of coefficients for each User / *Diasensor® 3000* combination.

Calibration Data - The spectral, sensor, and time stamp data from the *Diasensor® 3000* and the corresponding *HemoCue* monitor's glucose readings collected for the purpose of extracting Calibration Coefficients for a Glucose Measurement Algorithm.

Coarse Outlier - A subsession failing the Standard Deviation Check. During Calibration and Re-Calibration, the software performs the Standard Deviation Check.

Countable Calibration Session – A session that is valid and with at least one (1) valid subsession that is not a coarse outlier.

Countable Calibration Sitting – A sitting with at least four (4) countable Calibration sessions and a time stamp at least two (2) hours later than the time stamp of the most recent previous successful sitting. At least two (2) of the four (4) sessions must have been collected before the *HemoCue*, and at least two (2) of the four (4) sessions must have been collected after the *HemoCue*.

Hemocue 154?

HemoCue Reading - The event of performing one (1) measurement on the *HemoCue* monitor. A valid *HemoCue* result is a quantitative reading with a value between 0 and 400 mg/dL (0 to 22.2 mmol/L), the effective measurement range of a *HemoCue* monitor.

Outlier - In a set of data, a value so far removed from other values in the distribution that its presence could not be attributed to the random combination of chance causes.

Re-Calibration - The collection of Re-Calibration Data and the processing of the data to extract updated User Calibration Coefficients from both previously collected data and the newly collected Re-Calibration Data. The process of Re-calibration is identical to Calibration, except that the length of time during which data is collected and the amount of data collected are greatly reduced, and the Re-calibration Data is concatenated to previously collected data.

Re-Calibration Data - The spectral, sensor, and time stamp data from the *Diasensor® 3000* and the corresponding *HemoCue* monitor's glucose readings collected for the purpose of updating the Calibration Coefficients.

Session - The series of events starting when the User presses the start button <1> on the *Diasensor® 3000* and ending after the last action before the User can press the start button <1> again. ~~From a data acquisition point of view, a session is the time bracketed by two (2) reference~~ measurements and a final local dark measurement.

Sitting - The single event of a User sitting and collecting data and/or obtaining a glucose reading on the *Diasensor® 3000* and the *HemoCue* monitor, when necessary. A sitting in Calibration, Re-Calibration and Measurement differs in the nominal number of sessions performed per sitting. During Calibration and Re-Calibration, there is one (1) *HemoCue* reading for each sitting. During Measurement, there is no HemoCue reading other than normally scheduled quality monitoring.

Subsession - One (1) session may consist of several subsessions. A subsession is the time during which the *Diasensor® 3000* collects sixteen (16) individual spectra.

Valid Session - A session that is not ended prematurely by either the User or the *Diasensor® 3000* and therefore not resulting in a *"Problem Detected"* screen.

Valid Subsession - A subsession of a valid session in which all of the skin spectra time stamps are less than fifteen (15) minutes from a valid *HemoCue* time stamp.

Term	Description
DRD	*Diasensor® 3000* Non-invasive Glucose Monitor Design Requirement Document.
QM	Quality Monitoring
SDD	Software Design Description
SDP	Standard Deviation of Prediction
SEC	Standard Error of Calibration
SIC	Slope Intercept Correction
SRS	Software Requirements Specification
TOD	Time of Day

1.4 References

Following is a list of reference documents.

1. DRD_5399 6 *Diasensor® 3000* Gamma Non-Invasive Glucose Monitor Design Requirements
2. ????? *Diasensor® 3000* Patient Data Processing Software Design Description
3.
4.
5.
6.

1.5 Overview

The remainder of this document is divided into two sections.

1. Section 2 contains the general description of the *Diasensor® 3000* software and its relation to the system as a whole.
2. Section 3 describes all the software requirements as detailed in the DRD as well as requirements from other references.

2. General Description

A *Diasensor® 3000* must be calibrated for each User. To accomplish this, data is collected from both a *Diasensor® 3000* and an invasive glucose meter. When the specified amount of data has been collected, it is then used as input to the software that forms the Calibration.

The *Diasensor® 3000* is Re-Calibrated on a specific time schedule, or when the User experiences repeated Quality Monitoring failures. Re-Calibration is identical to Calibration, except that the length of time during which data is collected and the amount of data collected are greatly reduced. The Re-Calibration data is concatenated to previously collected data.

This section describes the general factors that affect the *Diasensor® 3000* software used for Calibration Re-Calibration, Glucose Measurement and Test and Diagnostic modes. This section does not state specific requirements.

Detailed design descriptions are described in the Software Design Description (SDD) document for the *Diasensor® 3000* unit.

2.1 System Functional Description

Hardware Interfaces -

Communications Interfaces -

User Interfaces -

2.2 User Characteristics

This software is ~~completely~~ automated. It will generate reports and send them to the Data Analyst for review.

2.3 General Constraints

1.
2.

2.4 Assumptions and Dependencies

Each User's data will be stored in a database so it can be easily located.

Avoid using column numbers when possible, using column names instead.

3. Diasensor® 3000 Software Requirements

3.1 Functional Requirements

3.1.1 Download Data

Requirement:

The software must be able to download the *Diasensor® 3000* data into the correct tables in the database. Each *Diasensor® 3000* must be able to download data for up to fifteen (15) Users.

Inputs:

Data downloaded from the *Diasensor® 3000* via the Internet to the database.

Processing:

Each day a program will run to download data from a single *Diasensor® 3000* to the correct tables in the database. The program will download data for up to fifteen (15) Users. Some checking of the incoming data will occur. If an error is found, a record will be stored in the database and written to the weekly report for the Data Analyst to review. When sufficient data has been collected, an alert will be stored in the database and written to the weekly report for the Data Analyst to review.

Outputs:

Diasensor® 3000 data downloaded to the correct tables of the database.
Errors downloaded to a table in the database and written to the weekly report.
Notification to the Data Analyst via the weekly report when sufficient data has been collected.

3.1.2 Generate Weekly Reports

Requirement:

The software will generate weekly reports, which the Data Analyst will review.

Inputs:

Analyst ID
Patient ID
Errors with Data
Standard Deviation of the HemoCue Readings
Diasensor® 3000 Spectral Data
Standard Deviation of subsession results
Diasensor® 3000 Absorbance Data

Processing:

Each week the software will generate a weekly report with the following information:

1. Patient Identification information.
2. Any errors encountered with the data.
3. The Standard Deviation of the HemoCue readings.
4. Message stating whether or not sufficient data has been collected.
5. Message if there is a need for a Re-Calibration.
6. Preliminary Plot (see 3.1.4 below)
7. A tally of the number of subsessions that have failed Standard Deviation and the percentage of subsessions that failed in relation to the total number of subsessions.

The software will then send the weekly report to the Data Analyst

Outputs:

A report for the Data Analyst to review.

3.1.3 Calculate the Standard Deviation of the HemoCue readings

Requirement:

The software will calculate the Standard Deviation of the HemoCue readings.

Inputs:

One HemoCue reading per sitting of spectral data.

Processing:

Use one (1) HemoCue reading per sitting to calculate the Standard Deviation of the HemoCue readings. The software shall write the result to the weekly report for review by the Data Analyst. If the Standard Deviation of the HemoCue is not greater than or equal to 40 mg/dL all other processing will stop.

Outputs:

The Standard Deviation of the HemoCue readings written to the weekly report that is sent to the Data Analyst.

3.1.4 Make Preliminary Plots

Requirement:

The software shall make the following preliminary plots and write them to the weekly report for the Data Analyst to review.

Inputs:

The *Diasensor® 3000* spectral data and associated HemoCue readings

Processing:

The software will make the following preliminary plots:

1) HemoCue readings versus data collection time
2) A histogram of the HemoCue readings
3) Mean *Diasensor® 3000* skin absorbance data versus channel
4) Standard Deviation of *Diasensor® 3000* skin absorbance data versus channel
5) *Diasensor® 3000* skin absorbance data versus channel (every 100th row)
6) Temperature sensors versus time
7) Mean Reference data versus channel
8) Standard deviation of Reference data versus channel
9) Raw Reference data versus channel
10) Mean absorbance of reference data versus channel
11) Standard deviation of reference absorbance data versus channel
12) Reference absorbance data versus channel
13) Mean *Diasensor® 3000* skin data versus channel
14) Standard deviation of *Diasensor® 3000* skin data versus channel
15) Raw *Diasensor® 3000* skin data versus channel (every 100th row)
16) Dark spectra versus time

Outputs:

The plots as described above written to the weekly report in the database which is sent to the Data Analyst.

3.1.5 Calculate the Standard Deviation

Requirement:

The software will calculate the Standard Deviation of each subsession and store the values in the correct table in the database. The software will then calculate the percentage of subsessions that fail in relation to the total number of subsessions. This percentage will be recorded on the weekly report for the Data Analyst to review.

Inputs:

The *Diasensor® 3000* spectral data.

Processing:

Let M denote the number of skin spectra in the set. Let S_{ij} denote a particular skin spectra pixel, where i denotes the spectra number {1..M} and j denotes the pixel number {1..64}.

Calculate the Standard Deviation of each subsession as follows.

1. Compute Standard Deviations of individual pixels: σ_j = STDEV (S_{1j}, S_{2j}, ... $S_{M,j}$) for j = 1 to 64.
2. Compute the average of the 64 Standard Deviations, denoted as σ_{AVG}.
3. If $\sigma_{AVG} < 0.009$, accept the sub-session. Otherwise, reject the sub-session.

The Standard Deviation for each subsession shall be written to the appropriate table in the database.

Also, a tally of the number of subsessions that have failed and the percentage they are of the total number of subsessions will be written to the weekly report for the Data Analyst to review. This percentage shall not exceed 30%.

Outputs:

The Standard Deviation of each subsession written to the database.

The percentage of subsessions that fail in relation to the total number of subsessions written to the weekly report for the Data Analyst to review.

3.1.6 Check for Sufficient Data

Requirement:

The software will check to see if there is sufficient Calibration/Re-Calibration data to continue forming a Calibration/Re-Calibration.

Inputs:

The *Diasensor® 3000* spectral data in an ASCII file

Processing:

Perform tests to check the Sufficient Calibration/Re-Calibration Data Criteria as follows:

The number of countable Calibration/Re-Calibration sessions must be greater than or equal to 600/70.

The number of countable Calibration/Re-Calibration sittings must be greater than or equal to 108/12. To count, a sitting must have at least four (4) sessions that have at least one (1) subsession each. The HemoCue time stamp must be at least two (2) hours later than the HemoCue time stamp of the most recent previous successful sitting.

The number of days with at least one (1) countable Calibration/Re-Calibration sitting must be greater than or equal to 54/6.

Outputs:

A message written to the weekly report in the database stating that sufficient data has been collected which is sent to the Data Analyst for review.

3.1.7 Convert Skin Spectrum to Absorbance

Requirement:

The software will average the skin spectra in each subsession, so there will be a maximum of four (4) skin spectra per session. The software will convert each average skin spectrum to absorbance units.

Inputs:

Diasensor® 3000 spectral data that has passed all error checks.

Processing:

Average the spectra in each subsession to give a maximum of four (4) spectra per session.

Convert each average skin spectrum to absorbance units by using the following equation:

$$\text{absorbance} = \log_{10}\left(\frac{\text{first reference reading}}{\text{skin reading}}\right)$$

Outputs:

Diasensor® 3000 absorbance data written to the database.

3.1.8 Produce the Calibration Vector

The software must be capable of producing a Calibration/Re-Calibration vector using Slope Intercept Corrected (SIC) Calibration method.

Inputs:

Diasensor® 3000 absorbance data

Processing:

The PLS Decomposition and Slope Intercept Correction Calibration Method will be used to produce the Calibration Vector.

Outputs:

The Calibration Vector and Calibration Constant

The Loadings Matrices (one (1) for each rank up to the Calibration rank used) and the Load Vector

3.1.9 Print Error Grid

Requirement:

The software will print an Error Grid of Calibration/Re-Calibration Self-predictions to the weekly report in the database when the Calibration/Re-Calibration is complete.

Inputs:

Diasensor® 3000 absorbance data

The Calibration Vector and Calibration Constant

Processing:

Print a Clarke Error Grid to the weekly report in the database when the Calibration/Re-Calibration is finished. The report will be sent to the Data Analyst for review. The Error Grid will compare the Calibration/Re-Calibration Self-predictions with the actual HemoCue readings. On the error grid, display the calculated Correlation Coefficient, the RMSEC (Root Mean Square Error of Calibration), the slope, and the Quality Monitoring Cutoff (QM Acceptable Range).

The Correlation Coefficient must be ≥ 0.7. The Quality Monitoring Cutoff is used when the Calibration File is created.

Determine the Quality Monitoring Cutoff Value as follows:

For paired Diasensor measurement (x_i) and HemoCue value (y_i) for data collected during calibration, define a Root Mean Square (RMS) Error of Calibration as follows.

$$\mathbf{RMS}_{\mathbf{Diasensor}} = \sqrt{\frac{1}{\mathbf{M}}\sum_{i=1}^{M}(\mathbf{y}_i - \mathbf{x}_i)^2} \quad \text{where M is the number of paired results}$$

$$QM\ cutoff\ value = 2 * RMS_{Diasensor}$$

Outputs:

A Clarke Error Grid printed to the weekly report in the database, which will be reviewed by the Data Analyst.

3.1.10 Notify Data Analyst of Calibration/Re-Calibration Completion

Requirement:

The software will notify the Data Analyst via the weekly report when sufficient data has been collected for the Calibration/Re-Calibration.

Input:

Alert that sufficient data has been collected for the Calibration/Re-Calibration.

Processing:

The software will download an alert that sufficient data has been collected for the Calibration/Re-Calibration. The software will then generate the final weekly report for this Calibration/Re-Calibration and send it to the Data Analyst to review whether the Calibration/Re-Calibration has passed or failed.

Output:

Final weekly report sent to Data Analyst for review of the status of the Calibration/Re-Calibration.

3.1.11 Make Calibration File

Requirement:

The software shall make the User Calibration/Re-Calibration File, which contains the User's Calibration Coefficients.

Inputs:

Notification from Data Analyst that Calibration/Re-Calibration has passed.

Diasensor® 3000 absorbance data

The Control Data

The Calibration Vector and Calibration Constant

The Loadings Matrices (one (1) for each rank up to the Calibration rank used)

The Load Vector

Processing:

The software shall build the User Calibration/Re-Calibration File and then send it to the *Diasensor® 3000* via the Internet. The essential components that the software will need to build the User Calibration/Re-Calibration File are as follows:

General:

1. The channel numbers to use, which shall be a parameter. The default will be 1 through 57. Fill the unused channels with zeros so there is a placeholder for all 64 channels.
2. The Calibration Date, use the current date.
3. The 4-digit distributor ID and 6-digit user ID, which shall be a parameter.

4. The Quality Monitoring flag, default to "T"
5. The QM Cutoff Value

Control Data:

1. Average Absorbance of control data.
2. The Average sensor readings collected at the same time the control data was collected, in Absorbance units.
3. The deviation that the current Control pixel measurements may drift from the maximum and minimum values of the Control average absorbance. The default is 0.003.

Skin Data

1. The Skin Prediction Matrix -- the Calibration for the patient, which contains the Calibration Vector, Calibration Constant, rank number (default = 57), and rank weight (default = 1)
2. The Number of Skin Prediction Ranks -- the number of ranks used when calculating a Glucose Measurement. There may be up to three (3) ranks used (default = 1)
3. The *Diasensor® 3000* Valid Measurement Range. (Default is 0-400 mg/dL)
4. The User Alert Range. (Default is 40-400 mg/dL)
5. The Mean of the Calibration Skin Spectra: calculate the Mean of the Calibration Skin Spectra, which is the average of all the columns of absorbance data
6. The Loadings Matrices
7. The Load Vector

Outputs:

The User Calibration/Re-Calibration File uploaded to the *Diasensor® 3000*.

4. Revision

Rev	Description	Author	Effective Date
AA	Initial document describing software requirements	Marie Polka	