Patient Data Analysis
Software Requirements Specification

Contents

1. General Description

1.1 Purpose

The purpose of this document is to define the software requirements specifications for the software used by Patient Data Analysis (PDA) when creating a *Diasensor 2000* Calibration or Re-calibration.

1.2 Definitions

1.2.1 Calibration

The collection of Calibration Data and the processing of the data to extract a patient's Calibration coefficients. The Calibration process does not include Evaluation and Re-Calibration.

1.2.2 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 patient for a single *Diasensor 2000*. This results in a unique set of coefficients for each patient / *Diasensor 2000* combination.

1.2.3 Calibration Data

The spectral, sensor, and time stamp data from the *Diasensor 2000* and the corresponding *HemoCue* monitor's glucose readings collected for the purpose of extracting Calibration coefficients for a glucose measurement algorithm.

1.2.4 Coarse Outlier

A subsession failing the standard deviation check. During Calibration, the Patient Data Analysis Section of Computational Analysis performs the standard deviation check. See the *Diasensor 2000* Algorithm Specification for a complete description of the standard deviation check.

1.2.5 Countable Calibration Session

Session that is valid and with at least one valid subsession that is not a coarse outlier.

1.2.6 Countable Calibration Sitting

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*.

1.2.7 .hc Object

An electronic file containing one *HemoCue* reading for each *Diasensor 2000* sitting of spectral data, in an S-Plus object format. The actual file extension is ".hc".

1.2.8 HemoCue Reading

The event of performing one 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.

1.2.9 Outlier

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

1.2.10 Re-Calibration

The collection of Re-Calibration Data and the processing of the data to extract updated patient 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.

1.2.11 Re-Calibration Data

The spectral, sensor, and time stamp data from the *Diasensor 2000* and the corresponding *HemoCue* monitor's glucose readings collected for the purpose of updating the calibration coefficients.

1.2.12 .ska Object

An electronic file containing spectral data from the *Diasensor 2000*, in an S-Plus object format. The actual file extension is ".ska".

1.2.13 Session

The series of events starting when the patient presses the start button <1> on the *Diasensor 2000* and ending after the last action before the patient can press the start button <1> again. From a data acquisition point of view, a session is the time bracketed by two reference measurements and a final local dark measurement.

1.2.14 Sitting

The single event of a patient sitting and collecting data and/or obtaining a glucose reading on the *Diasensor 2000* and the *HemoCue* monitor, when necessary. A sitting in Calibration, Evaluation, and Measurement differs in the nominal number of sessions performed per sitting. During Calibration and Evaluation, there is one *HemoCue* reading for each sitting. During Measurement, there is no HemoCue reading other than normally scheduled quality monitoring.

1.2.15 Subsession

One session may consist of several subsessions. A subsession is the time during which the *Diasensor 2000* collects sixteen (16) individual spectra, each preceded by a single dither.

1.2.16 Valid Session

A session that is not ended prematurely by either the patient or the *Diasensor 2000* and therefore not resulting in a *"Problem Detected"* screen.

1.2.17 Valid Subsession

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

1.3 Acronyms

.hc – S-Plus object of one *HemoCue* reading for each *Diasensor 2000* sitting (see definitions)

PDA -- Patient Data Analysis

QM -- Quality Monitoring

SDP -- Standard Deviation of Prediction

SEC -- Standard Error of Calibration

SIC -- Slope Intercept Correction

.ska – Spectral data in S-Plus format (see definitions)

SRS -- Software Requirements Specification

1.4 References

The following documents are incorporated by reference into this specification.

1. 32000-PD02 *Diasensor 2000* Algorithm, Product Specification
2. 32000-PU01 *Diasensor 2000* Data Acquisition, Product Use Procedure
3. 31257-PU01 *Diasensor 2000* Calibration, Product Use Procedure
4. 31256-PU01 *Diasensor 2000* Evaluation, Product Use Procedure
1. 31259-PU01 Patient Data Analysis, Product Use Procedure
5. 31184-FS01 *Diasensor 2000* User Card, Format Specification
6. 31170-ML01 *Diasensor 2000* User's Guide

2. Overall Description

2.1 Product Perspective

A *Diasensor 2000* must be calibrated for each patient. To accomplish this, data is collected from both a Diasensor and an invasive glucose meter. The data is transmitted to Patient Data Analysis. When the specified amount of data has been collected, it is then used as input to the software that forms the Calibration.

The patient then collects Evaluation data. This involves using the Calibration to collect glucose measurements from a *Diasensor 2000*, and simultaneously, collecting an invasive glucose meter. The data is transmitted to Patient Data Analysis. When the specified amount of data has been collected, it is then used as input to software used to determine if the *Diasensor 2000* and the Calibration coefficients are working effectively for the patient. Only after the paitent has passed Evaluation may the patient begin using the Diasensor in normal Measurement mode.

The *Diasensor 2000* 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, and the Re-calibration data is concatenated to previously collected data.

2.1.1 Hardware Interfaces

The software will be run on a UNIX based system.

2.1.2 Communications Interfaces

The analyst, working from a PC workstation connected to the local area network, uses Novell's LAN WorkPlace to gain access to the UNIX system. The UNIX system runs the Solaris operating system.

2.1.3 User Interfaces

This software is meant to be used by Patient Data Analysts, who are trained in the use of the S-PLUS programming language.

The Patient Data Analysts will be trained to run the software by directly invoking programs from their work station. The standard interface is S-PLUS version 3.3. S-PLUS "wrapper" programs may also be written as user interfaces for C or C++ programs. Other user interfaces may be approved on an individual basis.

2.2 Product Functions

1. This software is to be used by Patient Data Analysis to create *Diasensor 2000* Calibrations and Re-Calibrations.
1. This software is to be used by Patient Data Analysis to Evaluate if the *Diasensor 2000* and the Calibration coefficients are working effectively for the patient.
2. Software shall be designed to ensure the repeatability, reliability, and performance of the application or system according to its intended use.

2.3 User Characteristics

This software is intended for the use of data analysts in Patient Data Analysis. These analysts typically have at least two years of college background and often a bachelor's degree in a math or computer science discipline. They also must have strong computer work experience and extensive on-the-job training.

2.4 Constraints

1. The software shall be designed to run on the existing UNIX system.
2. At least seven Patient Data Analysts must be able to perform analysis simultaneously.

2.5 Assumptions and Dependencies

Each patient's data will be stored in a patient and device specific directory so it can be easily located. The Patient Data Analysts must exercise caution to ensure that the data is stored correctly.

Avoid using column numbers when possible, using column names instead. We will continue to use parameters containing the column numbers of the Diasensor channel numbers to be used. The default for the channel numbers will now be 1-57 (channels 1-57 will be used).

3. Specific Requirements

3.1 Functional Requirements

3.1.1 The software must be able to split the incoming Diasensor data into up to four files, one file for each of four possible patients that can use a Diasensor. It must also create an Alert file, indicating when enough data has been collected, when necessary.

3.1.1.1 Inputs

Data will be uploaded from the Diasensor via the Internet to the directory: /u8/*distributor ID*/*BICO Login ID*/*incoming* and the file name will be: mmddhh*mm*.PD.

where:

mm = data transfer month
dd = data transfer day
hh = data transfer hour
mm = data transfer minutes

The "BICO Login ID" is a shortened form of the Diasensor serial number.

3.1.1.2 Processing

Each day, a program will be run to split a file from a single Diasensor into as many as four files: One file of both SPECTRUM and READING data for each of four patients. These files will be built in the directory: /a1c/*distributor ID*/*patient ID*(6 digits max.)/*BICO Login ID*/src and the file name will be: mmddhh*mm*.bin

where:

mm = data transfer month
dd = data transfer day
hh = data transfer hour
mm = data transfer minutes

Some checking of the incoming data will occur. If an error is found, a record is logged in a file. This record shall include the date and time the data was collected, and type of error. The following are the checks:

1. Are the collection date and time stamps out of sequence?
2. Are the incoming sitting counts (records within the sitting) out of sequence?
3. Is there a missing spectral status code?

If an alert record is in the file, create an Alert file in an ASCII text format. The Alert file will be built in the directory: /a1c/*distributor ID*/*patient ID*(6 digits max.)/*BICO Login ID*/src and the file name will be: mmddhh*mm*.alert.txt. The Alert file will contain the following information:

Table 1: Alert File

Column	Field Name	Description	Range
1	distributorId	first 4 digits of the Bico_user_id	4 digits
2	userId	last 6 digits of the Bico_user_id	numeric, 6 digits max.

Column	Field Name	Description	Range
3	date	Date in the format: yyyymmdd	
4	time	Time in the format: hhmmss	
5	mode	instrument operating mode	1 = calibration 2 = evaluation 3 = measurement 4 = recalibration
6	status	alert status code	2 digits

3.1.1.3 Output

An Alert file, when necessary, called: mmddhh*mm*.alert.txt.

A file of the daily incoming data in the correct patient/BICO Login directory, called: mmddhh*mm*.bin.

An entry in an error log file, when necessary.

Note: Each day, each patient's binary files will be zipped into an appropriate file.

3.1.2 The software must be able to translate binary Diasensor data to S-PLUS format file(s) (objects).

3.1.2.1 Inputs

A patient's *Diasensor 2000* data in a binary format, from the file of zipped mmddhh*mm*.bin data.

Part of the output object name, as a parameter, the default being: Fyymmdd where:

"F" = literal, stands for Final.

yymmdd = date that the S-PLUS object was created

This will be concatenated with a letter which will indicate the mode the data was collected in, such as: "C" which stands for Calibration. The extension of the file will depend upon the type of data that was collected. Spectral data will have the extension ".ska", glucose measurement readings will have the extension ".rdg".

So, the entire file name would end up being: CFyymmdd.ska for a file of calibration spectra for a completed (final) calibration.

3.1.2.2 Processing

The analyst unzips the compressed file(s).

The analyst concatenates the appropriate mmddhh*mm*.bin files into a concatenated file, named mmdd.cat.bin, where:

mm = month the concatenated file was created

dd = day the concatenated file was created

.cat = literal, indicates this is a concatenated file

Translate the Diasensor binary spectral data from the concatenated file into an S-PLUS object, as follows:

Table 2: SKA Structure Format

Column	Field Name	Description	Range
1	spectrumType	Type of spectrum in data buffer. Type 3 = index is not really a spectrum type. It is used by protomgr for indexing.	0 = spectrum_status 1 = control 2 = dark 3 = index 4 = reference 5 = skin 6 =control_absorbance 7 = dark_absorbance 8 = ref._absorbance 9 = skin_absorbance
2	distributorId	first 4 digits of the Bico_user_id	4 digits
3	userId	last 6 digits of the Bico_user_id	numeric, 6 digits max.
4	date	Date in the format: yyyymmdd	
5	time	Time in the format: hhmmss	
6	invasive	Corresponding invasive meter reading	0 to 65,535
7	mode	instrument operating mode	1 = calibration 2 = evaluation 3 = measurement 4 = recalibration
8	sittCount	Sitting count. (the number of good spectrum status records for all the data (e.g. a whole Calibration)) or if all data is wanted, the number of spectrum status records.	1 – 65,535 The sitting number while using this mode of operation. (normally, cal. sittings would be 1-120).
9	sessCount	Session count	1 – 6 for Cal. or Re-cal., 1-1 for Evaluation or Measurement mode. The session number within the above sitting.
10	todCode	Time-Of-Day class code.	1 = before breakfast 2 = after breakfast 3 = before lunch 4 = after lunch 5 = before dinner 6 = after dinner 7 = bedtime 8 = night 9 = other
11	spectrum[1]	Spectral data of spectrum_type	up to 15 digits
12	spectrum[2]	Spectral data of spectrum_type	up to 15 digits
13-73	spectrum[3 to 63]	Spectral data of spectrum_type	up to 15 digits
74	spectrum[64]	Spectral data of spectrum_type	up to 15 digits
75	sensor[1]	sensor data	up to 15 digits
76	sensor[2]	sensor data	up to 15 digits
77-84	sensor[3 to 10]	sensor data	up to 15 digits
85	statusCode	error code from spectrum status	2 digits

Translate the Diasensor binary glucose measurement data from the concatenated file into an S-PLUS object, as follows:

Table 3: RDG Structure

Column	Field Name	Description	Range
1	distributorId	first 4 digits of the Bico_user_id	4 digits
2	userId	last 6 digits of the Bico_user_id	numeric, 6 digits max
3	mode	Instrument operating mode	1 = calibration 2 = evaluation 3 = measurement 4 = recalibration
4	date	Date in the format: yyyymmdd	numeric
5	time	Time in the format: hhmmss	numeric warning: no leading zeros
6	glucose	measured blood glucose (mg/dL)	-32,768 to 32,767
7	control	control sample (absorbance * 100,000)	-32,768 to 32,767
8	invasive	invasive meter measurement (mg/dL)	-32,768 to 32,767
9	todCode	Time-Of-Day class code	1 = before breakfast 2 = after breakfast 3 = before lunch 4 = after lunch 5 = before dinner 6 = after dinner 7 = bedtime 8 = night 9 = other
10	qmFlag	quality monitoring indicator; if nonzero, then this reading was used for QM purposes	0 or 1
11	status	measurement algorithm completion status code	Usage specific
12	correction	bias correction value used to get this measurement. in units of mg/dL	-32,768 to 32,767

Normally, only data from sittings with a status code indicating that it is good will be converted into S-Plus object(s). However, we also need an option to build an S-Plus object(s) that contains all the data, both good and bad data.

Other Checks:

1. Warn the analyst if the data collection time stamps are out of sequence, and display what the date and time was.
2. If the incoming sitting counts (records within the sitting) are out of sequence, warn the analyst and display the date and time where this occurs. Then, treat the data as if it were "bad".
3. If there is a missing spectral status code, warn the analyst and display the date and time where this occurs. Then treat the data as if it had a "bad" status.

3.1.2.3 Output

Diasensor 2000 data in S-PLUS format file(s) (objects).

If necessary, warnings that the data checks failed.

3.1.3 The software will create an S-PLUS object (.hc object) that contains one HemoCue reading per sitting of spectral data.

3.1.3.1 Inputs

The S-PLUS object of spectral data (.ska object)
The output object name, as a parameter.

3.1.3.2 Processing

Create an S-PLUS object containing a vector of one HemoCue reading for each sitting of spectral data.

3.1.3.3 Output

One *HemoCue* reading for each sitting of spectral data, in an S-PLUS format file (.hc object).

3.1.4 There will be software to create several preliminary plots.

3.1.4.1 Inputs

The spectral data and associated HemoCue readings in S-PLUS format (the .ska object).

3.1.4.2 Processing

The following plots will be created:

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

3.1.4.3 Outputs

Several plots, as described above.

3.1.5 The software will perform a Standard Deviation check and remove the subsessions that do not pass. It will then check to ensure that less than or equal to 30% of the data was removed due to Standard Deviation errors.

3.1.5.1 Inputs

The spectral data in S-PLUS format (the .ska object).

3.1.5.2 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}.

Perform the Standard Deviation Check 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.

Also, the number subsessions failing the standard deviation check (Coarse Outliers) must be less than or equal to 30% of the total valid subsessions. For example:

invalid $\leq$ 0.3 * total

Display the total number of subsessions, the number of subsessions that failed the standard deviation check, and whether this check passed.

3.1.5.3 Outputs

An .ska object containing only the subsessions that passed the Standard Deviation check.

A message containing the total number of subsessions, the number of subsessions that failed, and whether this data set passed the Standard Deviation check.

3.1.6 The software will calculate and display the standard deviation of the HemoCue readings.

3.1.6.1 Inputs

The HemoCue readings in S-PLUS format (the .hc object).

3.1.6.2 Processing

Use one HemoCue reading per sitting to calculate the standard deviation of the HemoCue readings. Display the standard deviation of the HemoCue readings. If the standard deviation is not greater than or equal to 40 mg/dL, the analyst will discontinue processing.

3.1.6.3 Outputs

Display the standard deviation of the HemoCue readings.

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

3.1.7.1 Inputs

The spectral data in S-PLUS format (the .ska object).

3.1.7.2 Processing

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

The number of countable Calibration sessions must be greater than or equal to 600.

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

The number of days with at least 1 countable Calibration sitting must be greater than or equal to 54.

3.1.7.3 Outputs

Messages to the analyst that indicate whether or not the data passed the sufficient Calibration data criteria.

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

3.1.8.1 Inputs

The .ska object containing the cleaned Diasensor data.

The output file name, as a parameter.

3.1.8.2 Processing

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

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

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

3.1.8.3 Outputs

An absorbance object of averaged data, in the same format as the .ska object.

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

3.1.9.1 Inputs

The absorbance object (.abs object).

3.1.9.2 Processing

See the *Diasensor 2000* Algorithm Product Specification, sections on PLS Decomposition and Slope and Intercept Correction Calibration Method for the details of performing the PLS decomposition and updating the calibration vector using SIC.

3.1.9.3 Outputs

The Calibration vector and calibration constant. The Loadings Matrices (one for each rank up to the Calibration rank used), and the Load Vector. All of these will be saved so they can be input into the skin library program without re-creating them.

3.1.10 The software will print an Error Grid of Calibration Self-predictions.

3.1.10.1 Inputs

The absorbance object.

The Calibration Vector and Calibration Constant.

3.1.10.2 Processing

Print a Clarke error grid, comparing the 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 will allow the patient data analyst to determine if the correlation is $\geq$ 0.7. The Quality Monitoring Cutoff is used when the Skin Library 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 as follows.

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

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

3.1.10.3 Outputs

A Clarke error grid, which shows the calculated correlation coefficient, the RMSEC, the slope, and the QM Cutoff (QM Acceptable Range).

3.1.11 The software must enable the analyst to create a patient skin library, which contains the patient's Calibration coefficients.

3.1.11.1 Inputs

The absorbance object.

The .ska object (used only for the Control data).

The Calibration vector, and Calibration constant.

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

The Load Vector.

3.1.11.2 Processing

The software must build the patient skin library. The essential components that the software will need to build the patient skin library 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

4. The Skin Prediction Matrix -- the Calibration for the patient, which contains the Calibration vector, Calibration constant, rank number (default = 25), and rank weight (default = 1).
5. The Number of Skin Prediction Ranks -- the number of ranks used when calculating a glucose measurement. There may be up to three ranks used (default = 1).
6. The *Diasensor 2000* Valid Measurement Range. (Default is 0-400)

7. The patient Alert Range. (Default is 40-400)
8. 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.
9. The Loadings Matrices.
10. The Load Vector.

3.1.11.3 Outputs

The patient's skin library.

3.1.12 The software must check if there is sufficient Evaluation data to verify the success of the Calibration, and inform the user of the result.

3.1.12.1 Inputs

Diasensor 2000 measurements in an S-PLUS format file (.rdg object).

3.1.12.2 Processing

Perform tests to check if there is sufficient Evaluation data as follows:

Number of days with at least one (1) countable Evaluation sitting should be greater than or equal to twenty five (25).

Number of countable Evaluation sittings should be greater than or equal to forty-nine (49).

Sittings with a status code other than zero(0), eighteen(18), and nineteen(19) are not countable.

3.1.12.3 Outputs

Messages to the user that indicate whether or not the data passed the sufficient Evaluation data criteria.

3.1.13 The software shall calculate the mean of the absolute values of the differences between the paired *HemoCue* and *Diasensor 2000* measurements. The software shall calculate a 95% confidence interval and compare the result to a threshold of 90, beyond which the Evaluation is said to have failed.

3.1.13.1 Inputs

Diasensor 2000 measurements in an S-PLUS format file (.rdg object). This file also contains the corresponding *HemoCue* reading.

3.1.13.2 Processing

z_α is such that the integral of the standard normal density from $z_{\alpha/2}$ to infinity equals $\alpha/2$.

$\bar{\mu}$ is the estimate of the mean absolute value of the error.

σ is the sample variance.

Assuming that the absolute value of the error is:

$$x_m = |Diasensor - HemoCue|$$

The estimate of the mean absolute value of the error is:

$$\bar{\mu} = \frac{1}{M}\sum_{m=1}^{M}|x_m|$$

The sample standard deviation is:

$$\sigma = \sqrt{\frac{\sum_{m=1}^{M}(x_m)^2 - M(\bar{\mu})^2}{M-1}}$$

The upper boundary of the confidence interval must be less than the threshold of 90 to pass Evaluation:

$$\bar{\mu} + z_\alpha \frac{\sigma}{\sqrt{n}} < threshold$$

3.1.13.3 Outputs

The upper boundary of the confidence interval.

Display a Pass or Fail status to the analyst, to be included in the Physician's report.

3.1.14 The software must enable the analyst to create a Physician's report containing the results of the Evaluation.

3.1.14.1 Inputs

Diasensor 2000 measurements in an S-PLUS format file (.rdg object). This file also contains the corresponding *HemoCue* reading.

3.1.14.2 Processing

Calculate and save the following, so they may be included on the Physician's report:

1. An analysis of the relative error between the average Diasensor 2000 and HemoCue readings.
2. A regression analysis of the Diasensor 2000 vs. HemoCue individual readings. Store the Correlation Coefficient, Standard Error, Slope, Intercept, and the number of glucose readings.
3. A plot displaying the Diasensor 2000 vs. HemoCue individual readings.

3.1.14.3 Outputs

A file containing the above data to be included in a Physician's report.