BIOCONTROL TECHNOLOGY INC.

TECHNICAL REPORT

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RECORD #
172

TITLE	FILENAME	REVISION
Patient Data Analysis Software Validation	000321dg.doc	
PROJECT OR PROGRAM NAME	PROGRAM ROOT NUMBER	
Diasensor 2000	52	
PROGRAM TASK DESCRIPTION	PROGRAM TASK NUMBER	
Patient Data Analysis Software Development	99	
NAME	DEPARTMENT	DATE
Diane Griffith	Comp. Analysis	03/21/00

TECHNICAL AREA

Patient Data Analysis

SUBJECT AND KEY TECHNICAL WORDS

Patient Data Analysis Software Verification and Validation

DOCUMENTATION TYPE

☒ Validation	☐ Error Budget	☐ Reliability	☐ Sensitivity
☒ Verification	☐ Product Support	☐ Risk Analysis	☐ Other

ASSOCIATED REPORTS

31259-SS, 31259-SD, Diasensor 2000 Patient Data Analysis Software Validation Plan; 000321dg.zip, data files

ABSTRACT

This report details the results of the Patient Data Analysis (PDA) Software Validation.

Background

This report documents the results of the initial Verification and Validation done on the Diasensor 2000 Patient Data Analysis Software.

Introduction

The Diasensor 2000 Patient Data Analysis Software Validation Plan was used to perform verification and validation. The results of these tests are reported below.

Purpose

To document the results of the Diasensor 2000 Patient Data Analysis Software verification and validation.

Description of Apparatus and Setup

Equipment Used

This software was developed and tested on the Sun ES-4000 UNIX computer (host name mule). The applications are invoked from the S-Plus environment.

Software Testers

The following people performed software testing:

Name	Initials
Marie Polka	MP
Qing Sun	QS
Vladimir Zhuze	VZ

Existing Conditions

Programs were tested during normal working hours on the ES-4000 or PC hardware.

Diagram of Apparatus

N/A. No special apparatus or equipment was used to conduct these tests.

Procedure of Experiment

The software applications were tested using sample data sets. Details of each test and the data used for the tests are listed in the Summary of Data and Results section of this report.

Summary of Data and Results

Validation Plan Section: 4.1.1

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.

1. Confirm that an entry is created for the error and that it is included in the error log.
2. Confirm that the software correctly splits the data into one file for each patient.
3. Confirm that at least one file contains both reading and spectral data.
4. Confirm that the data files are in the correct directory.
5. Confirm that the software creates an Alert file.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	split.tcl	01270401.PD	3/31/00,VZ	P
2	split.tcl	01191710.PD	4/03/00,VZ	P
3	split.tcl, load.objects	02240401.PD	3/31/00,VZ	P
4	split.tcl	02240401.PD	3/31/00,VZ	P
5	split.tcl	ALERT.PD	4/01/00,VZ	P

Comments:

1. 01270401.PD was run through split.tcl. As a result, a file 01270401.bin was created and placed in the proper directory. The entry of this action was recorded in a file 01270401.log in the source directory. An unexpected change in sitting count was also recorded in the log file (it usually indicates a missing spectrum status in the source file).
2. 01191710.PD was run through split.tcl. Since the source file contained data for 2 patients, two files with the same name 01191710.bin were created in the following directories: /a1c/102/0/b90ut066/src and /a1c/102/1/b90ut066/src. As one can see, the only difference in these names is a patient ID (0 vs. 1).
3. 02240401.PD was run through split.tcl. Since the source file contained data for only 1 patient in evaluation mode, only one file (02240401.bin) with binary data was created. The output file (02240401.bin) was used later as an input for SPLUS function load.objects and it split it in two objects: one with spectral data (ef000331.ska) and another with readings data (ef000331.rdg), so the original file had both spectral and reading data.
4. 02240401.PD was run through split.tcl. As a result, a file 02240401.bin was created in the following directory: /a1c/101/1/b90ut065/src. The directory name meets its specification in SRS.
5. ALERT.PD was run through split.tcl. As a result, alert.alert.txt was created in /a1c/101/1/b90ut065/src directory and this action was recorded in a log file alert.log in the source directory.

Validation Plan Section: 4.1.2

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

1. Confirm that reading data is placed in a file with the extension: .rdg, and is in the correct format.
2. Confirm that spectral data is placed in a file with the extension: .ska, and is in the correct format.
3. Confirm that the output file name parameter can be used.
4. Confirm that the output file names use the convention of adding a letter to the file name parameter to indicate the mode the data was collected in, e.g. "C"alibration, "E"valuation, etc.
5. Confirm that the software warns the user of problems, such as the date and time stamp being out of sequence.
6. Confirm that normally, only "good" data (data with status codes 0, 18, 19) is translated, but that a parameter can be used to override this and get all the data.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	Load.objects	02240401.bin	03/31/00, VZ	P
2	Load.objects	02240401.bin	03/31/00, VZ	P
3	Load.objects	02240401.bin	03/31/00, VZ	P
4	Load.objects	02240401.bin	03/31/00, VZ	P
5	Load.objects	01270401.bin	03/31/00, VZ	P
6	Load.objects	01270401.bin	03/31/00, VZ	P

Comments:

1. 02240401.bin was run through load.objects. As a result of its execution, an SPLUS object containing glucose readings, ef000331.rdg was created. The structure of this object is in the correct format with regard to the structure definition for RDG object.
2. 02240401.bin was run through load.objects. As a result of its execution, an SPLUS object containing spectral readings, ef000331.ska was created. The structure of this object is in the correct format with regard to the structure definition for SKA object.
3. Load.objects was run for 02240401.bin to test the alternative output filename parameter ("t000330"). As a result of the execution, the following SPLUS objects were created : et000330.ska and et000330.rdg. Both names follow the convention used for naming SKA and RDG objects.
4. 02240401.bin was run through load.objects. As a result of its execution, the following SPLUS objects were created: ef000331.ska and ef000331.rdg. Both names follow the convention used for naming SKA and RDG objects.
5. 01270401.bin was run through load.objects. The missing spectrum status for one sitting was recorded in all the spectra for this sitting (SPLUS ska object cf000331.ska).
6. 01270401.bin was run through load.objects. The status code field contents does show that only "good" data was used to create SPLUS objects. When the anyObjects parameter was set to true (false by default), "bad" sittings were also recorded in addition to "good" data.

Validation Plan Section: 4.2.1

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

1. Confirm that the output file name parameter can be used.

2. Confirm that a vector of HemoCue data is placed in an S-PLUS format file, and that there is one HemoCue record for each sitting of spectral data.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.hemo	c6098.ska, short.ska	3/31/00, MP	P
2	d2k.hemo	c6098.ska, short.ska	3/31/00, MP	P

Comments:

1. After running both c6098.ska and short.ska through d2k.hemo, the output file name and location were checked. The files were written to the proper directory, each with the output parameter name. The output file names are c6098.hc and short.hc
2. C6098.ska and short.ska were run through d2k.hemo. The output files were c6098.hc and short.hc. Both files are vectors. The files were found to have one HemoCue record for each sitting of spectral data after comparing them to their respective ska files.

Validation Plan Section: 4.2.2

There will be software to create several preliminary plots.

The Preliminary Plots are not absolutely necessary for the Calibration process; they are used for informational purposes. The software to create the plots is not yet complete. It will be tested upon completion.

Validation Plan Section: 4.2.3

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

1. Confirm that the HemoCue standard deviation is displayed to the user.
2. Confirm that for every HemoCue listed in the .hc file, there is at least one matching HemoCue reading in the D1000 data.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	stdev	c6098.hc	3/23/00, MP	P
2		c6098.hc, Cw8103.3m.ha.ha.016	3/23/00, MP	P

Comments:

1. The program stdev is a built-in S-PLUS function which has been tested in the past. The file c6098.hc is a vector of HemoCue readings for the calibration. When run through stdev, the Standard Deviation of the HemoCue is displayed to the screen.

2. A hand comparison of c6098.hc and the HemoCue column of Cw8103.3m.ha.ha.016 shows that for every HemoCue reading in c6098.hc, there is at least one matching HemoCue reading in Cw8103.3m.ha.ha.016.

Validation Plan Section: 4.2.4

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.

1. Confirm that .ska objects containing only the subsessions that passed the Standard Deviation check are created, and that the results are quite similar. The results may not be identical because the D1000 software creates subsessions based on a time break, the D2000 software creates subsessions based on the number of spectra (16). The D1000 software may throw out some subsessions that the D2000 software does not.
2. Confirm that a message containing the total number of subsessions, the number of subsessions that failed, and whether this data set passed the Standard Deviation check is output, and that the results are quite similar, as stated above.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	refmt, d2k.calproc	old_103.ska, oldn_103.ska, c6098.ska	3/22/00, MP	P
2	refmt, d2k.calproc, coarse.check	oldn_103.ska, c6098.ska	3/22/00, MP	P

Comments:

1. Old_103.ska was run through refmt, and c6098.ska was run though d2k.calproc. Due to the difference in the way subsessions are created, the Standard Deviation Check varied in 3 places. Because there was not sufficient time between subsessions, refmt counted 3 less subsessions and the Standard Deviations varied in these areas. The results are stored in refmt.txt and calproc.txt. To facilitate the rest of the validation process, the subsessions in old_103.ska that did not have sufficient time between them were altered. The new file is named oldn_103.ska. After altering the times to allow for sufficient time between subsession, oldn_103.ska was run through refmt. The results of this Standard Deviation test are identical to those of d2k.calproc. The results of running oldn_103.ska through refmt are found in refmtn.txt. The output of refmt and d2k.calproc are new ska files with only the subsessions passing the Standard Deviation Check.
2. A message containing the necessary information is displayed. A comparison of D1000 and D2000 data can be found in refmtn.txt and calproc.txt. The number of subsessions that failed, the number remaining and the total number are identical for the 2 files used. A message is also displayed as to whether or not the data set passed the Standard Deviation Check. A comparison of D1000 and D2000 results can be found in coarse.txt and calproc.txt.

Validation Plan Section: 4.2.5

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

1. Confirm that the software displays messages indicating how many of each item in each criteria there were in the Calibration, and how many were still needed to pass each criteria.
2. Confirm that the number of days and countable sessions and sittings are very similar for the D1000 and D2000 data. The results may not be identical because the D1000 software creates subsessions based on a time break, the D2000 software creates subsessions based on the number of spectra (16). The D1000 software may throw out some subsessions that the D2000 software does not. If there is any question about the results, calculate each: sessions, sittings and days.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.calproc	c6098.ska, short.ska	3/22/00, MP	P
2	d2k.calproc, cal.check	c6098.ska, Cw8103.3m.ha.ha.016	3/22/00, MP	P

Comments:

1. C6098.ska and short.ska were run through d2k.calproc. The results for c6098.ska, where there was sufficient calibration data can be found in calproc.txt. There are messages displaying how many of each item there are and that the data passes for that check. The results for short.ska, where there was insufficient calibration data can be found in short.txt. There are messages displaying how many of each item there are, that the data fails the check, and how many more of that item are needed.
2. C6098.ska was run through d2k.calproc, and Cw8103.3m.ha.ha.016 was run through cal.check. For the number of countable calibration sittings, the programs differed by 2. For number of countable sessions, the programs were identical. For number of countable days, the programs differed by 1. The overall number of sittings for each file differed by 8. This is due to the way the sitting column was made. For D1000 data, the program sitting uses a time break. Normally, for D2000 data, the sitting column is calculated in the D2000 program load.objects. Load.objects uses the sitting number transferred from the D2000, but continues to increment that number each time it changes for the entire data set to give the total number of sittings collected in this mode. But, for this D2000 file, the sitting column was hand counted and hand entered. Either method would account for the differences. The numbers for each item are easily verified when hand calculating them using short.ska.

Validation Plan Section: 4.2.6

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.

1. Compare the averaged absorbance objects and confirm that they are quite similar. The results may not be identical because the D1000 software creates subsessions based on a time break, the D2000 software creates subsessions based on the number of spectra (16). The D1000 software may throw out some subsessions that the D2000 software does not.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	mkAbsObj.tcl, check	c6098.ska, oldn_103.ska, oldn_103.ysi	3/23/00, MP	P

Comments:

1. The HemoCue columns and date columns of the 2 absorbance objects were compared by hand and found to be identical. The S-PLUS program compare was used to verify that the channel columns and sensor columns were comparable. After using the compare program to compare Sensors 1 and 10 of the D1000 formatted data to Sensors 1 and 10 respectively of the D2000 formatted data, they were found to be identical. Channels 1-4, 35, 47, 57, 60 and 64 were randomly chosen to compare the spectra. Channels 1-4, 35, 47 and 57 were found to be identical to 6 decimal places between the D1000 formatted data and the D2000 formatted data. Channels 60 and 64 were found to be identical to 4 decimal places. The differences beyond the specified decimal places for each channel are miniscule. Also, most of the spectra in each channel were identical if more decimal places were used. The above decimal places are where all spectra are identical.

Validation Plan Section: 4.2.7

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

1. Confirm that the D2000 software saves three files: one for the calibration vector and constant, one for the PLS loadings, and one for the Load Vector.
2. Confirm a parameter is used to indicate how many of the PLS loadings should be saved. Set the parameter to 25.
3. Confirm that the files are in the correct format, as follows:

- The Calibration constant and Calibration vector are stored in an object named: cal.vec. The first column in cal.vec is the Calibration constant, the Calibration vector is stored in columns 2 through 65.
- The PLS Loadings are stored in an object named: pls.load. There is one row for each rank up to the parameter number. The first column in each row of pls.load is the constant, the PLS Loadings are stored in columns 2 through 65.
- The SVD Load vector is stored in an object named: svd.load, in columns 1 through 64.

4. Compare the calibration vectors and calibration constants of the D1000 and D2000 software, and confirm that they are quite similar. A difference may occur because for the D1000 software, we used a time-based break on subsession. For the D2000 software, we break based on the number of spectra in a subsession, which are 16.
5. Confirm that the PLS loadings and the Load Vector of the D1000 and D2000 data are quite similar. A difference may occur for the same reason as stated above.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.calparam	c6098.abs, test851.rev	3/27/2000 / QS	Pass
2	d2k.calparam	c6098.abs, test851.rev	3/28/2000 / QS	Pass
3a	d2k.calparam	test851.rev	3/28/2000 / QS	Pass
3b	d2k.calparam	test851.rev	3/28/2000 / QS	Pass
3c	d2k.calparam	test851.rev	3/28/2000 / QS	Pass
4	d2k.calparam, opt.meth	test851, Cwb851.22.na.na.016	3/28/2000 / QS	Pass
5	d2k.calparam, skinlib.opt	test851.rev, Sib851.22.na.na.016	3/28/2000 / QS	Pass

Comments:

1. C6098.abs and test851.rev were run through d2k.calparam, respectively. Three files, named as cal.vec, pls.load and svd.load were saved in the following directory: */a1c/distributor ID/patient ID/BICO Login ID*. The file, cal.vec, is for the calibration vector and constant, the file, pls.load, for the PLS loading and the file, svd.load, for the leverage loading. The results for 851 are stored in bvec851.txt, plsload851.txt and svdload851.txt. The results for c6098.abs are stored in calparam.txt.
2. C6098.abs and test851.rev were run through d2k.calparam with the parameter *ranks* equal to 25, respectively. There are 25 PLS loadings stored in the file, pls.load. The results can be found in plsload851.txt and calparam.txt.
3. Test851.rev was run through d2k.calparam twice with parameter, ranks = c(20,25,30,40) and ranks = c(30,50), respectively. The results were stored in the file test851b.txt and test851c.txt. The files are in the correct format, as follows:
   - The Calibration constant and Calibration vector are stored in cal.vec. There is one row for each rank. The first column in cal.vec is the Calibration constant and the calibration vector is stored in column 2 through column 65.
   - The PLS loadings are stored in pls.load. There is one row for each rank from rank 1 up to the highest rank (rank 40 at first run, refer to test851b.txt). If the highest rank of the parameter, ranks, is set greater than 45, the PLS loadings are stored from rank 1 to rank 45 (rank 45 at second run, refer to test851c.txt). The first column in each row of pls.load is the constant, the PLS loadings are stored in column 2 through column 65.
   - The SVD load vector is stored in svd.load, in columns 1 through 64.
4. Test851 was run through d2k.calparam with the parameters ranks = 25 and num.spec = 16:58. Cwb851.22.na.na.016 was run through opt.meth with the argument, select = "sic". The results were stored in bvec851a.txt. For the Calibration vector and constant, the programs were identical.

5. Test851.rev was run through d2k.calparam with the parameters rank = 25 and num.spec = 7:49 (num.spec7:49 of flipped spectra are equivalent to num.spec 16:58 of original spectra). The results were stored in plsload851.txt. The PLS loadings between pls.load and 9885_851.slb generated by skinlib.opt and stored in skin library were identical to at least 10 decimal places. The leverage loadings between svd.load and 9885_851.slb were identical to at least 9 decimal places. The results were stored in svdload851.txt. The difference occurred because of the different length of decimal output.

Validation Plan Section: 4.2.8

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

1. Compare the D1000 Error Grid with the D2000 Error Grid. They should be similar, although they may not be identical because the D1000 software creates subsessions based on a time break, the D2000 software creates subsessions based on the number of spectra (16). The D1000 software may throw out some subsessions that the D2000 software does not.
2. Compare the correlation coefficient, the RMSEC (Root Mean Square Error of Calibration, a.k.a. SEP), and the slope. They should be similar, although they may not be identical for the same reason as above.
3. Compare the Quality Monitoring Cutoff printed on the D2000 error grid with the Quality Monitoring Cutoff of the D1000 data, which should be (2 * $RMSEC_{D1000}$).
4. Compare the QM Cutoff value, stored in the file qm.cutoff with the QM Cutoff printed on the D2000 error grid. They should be identical.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.calparam, opt.meth	test851, Cwb851.22.na.na.016	3/29/2000 QS	Pass
2	d2k.calparam, opt.meth	test851, Cwb851.22.na.na.016	3/29/2000 QS	Pass
3	d2k.calparam	test851	3/29/2000 QS	Pass
4	D2k.calparam	Test851	3/29/2000 QS	Pass

Comments:

1. Test851 was run through d2k.calparam. Cwb851.22.na.na.016 was run through opt.meth. The Error Grid generated by d2k.calparam was similar to that generated by opt.meth. The results were stored in test851.eps and test851b.eps.
2. Test851 was run through d2k.calparam and Cwb851.22.na.na.016 was run through opt.meth. The correlation coefficient, the RMSEC and the slope in both Error Grid plots were exactly the same.
3. Test851 was run through d2k.calparam. A Quality Monitoring Cutoff (QM Cutoff) was printed on Error Grid plot. The value of the QM Cutoff was equal to 2 * $RMSEC_{D1000}$.
4. Test851 was run through d2k.calparam. A file named qm.cutoff was saved in the directory: */a1c/distributor ID/patient ID/BICO Login ID*. The value in qm.cutoff was exactly the same as the value printed on Error Grid plot. The result was stored in qm851.txt.

Validation Plan Section: 4.2.9

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

1. Confirm the accuracy of the control average absorbance. Calculate the absorbance of two randomly chosen control spectra. Calculate the average of the two absorbance records. Create a subset of the data that contains the same two control readings. Run this file through the D2000 software. Compare to the hand calculated data, both absorbances and average absorbances. They should be identical.
2. Confirm the accuracy of the average absorbance of the sensor readings collected at the same time as the control. Calculate the absorbance of two randomly chosen control sensor spectra. Calculate the average of the two absorbance records. Create a subset of the data that contains the same two control sensor readings. Run this file through the D2000 software. Compare to the hand calculated data, both absorbances and average absorbances. They should be identical.
3. Confirm that the Calibration Vector, Calibration Constant, PLS Loadings, Load Vector, and QM Cutoff value were correctly stored.
4. Compare the D1000 and D2000 Mean of the Calibration Skin Spectra. They should be similar, although they may not be identical because the D1000 software creates subsessions based on a time break, the D2000 software creates subsessions based on the number of spectra (16). The D1000 software may throw out some subsessions that the D2000 software does not.
5. Confirm that the following were stored correctly:
    - The Calibration Date, the date the file was created.
    - The Sensor Ranges (rangeSensors), low and high point pre-set to 99.
    - Leverage tolerance, pre-set to 1.
    - LOF tolerance, pre-set to 1.
    - Distance tolerance, pre-set to 0.
    - A slope correction number, pre-set to 1.
    - A bias correction number, pre-set to 0.
    - The channel numbers to be used, default = 1-57
    - The total number of channels, default = 64
    - The *Diasensor 2000* Valid Measurement Range. (Default is 0-400)
    - The patient Alert Range. (Default is 40-400)
    - 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.
    - The rank number (default = 25), and rank weight (default = 1)
    - The Quality Monitoring flag, default = "T"

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.skinlib	conabs	3/29/00, MP	P
2	d2k.skinlib	conabs	3/29/00, MP	P
3	d2k.skinlib	cal.vec, pls.load, svd.load, qm.cutoff	3/29/00, MP	P
4	d2k.skinlib, skinlib.opt	c6098.ska, c6098.abs, Si8103.3m.ha.ha.016, oldn_103.ska	3/29/00, MP	P
5a	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5b	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5c	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5d	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5e	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5f	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5g	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5h	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5I	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5j	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5k	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5l	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5m	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P
5n	d2k.skinlib	c6098.ska, c6098.abs	3/29/00, MP	P

Comments:

1. Conabs contained 2 sessions from the file c6098.ska. This file was run through d2k.skinlib, and the control average absorbance for this file is stored in concheck.slb. The controls and first references were extracted from conabs, and the control average absorbance was hand calculated and stored in mlrefcon. The hand calculated control average absorbance and the one made by d2k.skinlib were identical to 12 decimal places.
2. Conabs contained 2 sessions from the file c6098.ska. This file was run through d2k.skinlib, and the average absorbance of the sensor readings for this file is stored in concheck.slb. The controls and first references were extracted from conabs, and the average absorbance of the sensor readings was hand calculated and stored in mlrefsens. The hand calculated average absorbance of the sensor readings and the one made by d2k.skinlib were identical to 17 decimal places.
3. The files cal.vec, pls.load, svd.load and qm.cutoff, which store the Calibration Vector, Calibration Constant, PLS Loadings, Load Vector, and QM Cutoff value respectively were run through d2k.skinlib. D2k.skinlib produced 103_d2000.slb, which stored these files. The files were identical to what was stored in 103_d2000.slb, therefore the files were stored correctly.
4. C6098.ska and c6098.abs were run through d2k.skinlib to test the D2000 data, while Si8103.3m.ha.ha.016 and oldn_103.ska were run through skinlib.opt to test the D1000 data. The D1000 results are stored in 103_d1000.slb and the D2000 results in 103_d2000.slb. The Mean of the Calibration Skin Spectra was found to be identical to 5 decimal places in both files.

5. C6098.ska and c6098.abs were run through d2k.skinlib. The file 103_d2000.slb was checked for correct storage of all parameters and pre-set numbers listed above. All were found to be stored correctly.

Validation Plan Section: 4.3.1

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

1. Confirm that the following are displayed to the analyst: the number of countable Evaluation sittings, the number of days with at least 1 countable Evaluation sitting, and the number of each still needed to pass the sufficient Evaluation data criteria.
2. Calculate the numbers to ensure they match the software. Remember: Sittings with a status code other than zero(0), eighteen(18), and nineteen(19) are not countable. The sufficient Evaluation data criteria are 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).

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.suffeval	c6098.rdg, half.rdg	3/24/00, MP	P
2a	d2k.suffeval	c6098.rdg, half.rdg	3/27/00, MP	P
2b	d2k.suffeval	c6098.rdg, half.rdg	3/27/00, MP	P

Comments:

1. C6098.rdg was D1000 data formatted to a D2000 .rdg file. This file was run through d2k.suffeval. The numbers for countable days and countable sittings were displayed to the screen. For c6098.rdg, there was sufficient data, so the program displayed this and told the user to continue processing. Then c6098.rdg was cut in half to make half.rdg. This file was run through d2k.suffeval. The numbers for countable days and sittings and the number still needed for each were displayed to the screen. The program informs the user to inform customer service. When the file was made, the status code column contained 0's, 18's, 19's and other codes to ensure the program would only pick out the good data. The results can be found in suffeval.txt.
2. For each run of d2k.suffeval, the number of countable calibration days and the number of countable calibration sittings were both computed by hand and then compared to the programs results. The comparison ended in the results being identical. The program removed any sittings with status code other than 0, 18 or 19.

Validation Plan Section: 4.3.2

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.

1. Confirm that the threshold parameter and output file name parameter can be used.
2. Create a subset of data. Using this subset, hand calculate the mean of the absolute values of the difference between the paired HemoCue and D2000 measurements. Calculate a 95% confidence interval and compare the result to a threshold of 90. Run the D2000 software that performs this function also using the subset of data. Compare the results. They should be identical.
3. Confirm that the calculated upper boundary of the confidence interval is displayed.
4. Confirm that a Pass or Fail status is displayed.
5. Confirm that a text file is created in the correct directory which contains the following:

- Distributor ID, User ID
- .rdg file name
- Threshold used
- Confidence Interval calculated
- "Evaluation Status:" (Pass or Fail)

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.ubofci	EF980215.rdg	3/29/2000 QS	Pass
2	d2k.ubofci	short.rdg	3/29/2000 QS	Pass
3	d2k.ubofci	short.rdg	3/29/2000 QS	Pass
4	d2k.ubofci	short.rdg	3/29/2000 QS	Pass
5a	d2k.ubofci	EF980215.rdg	3/29/2000 QS	Pass
5b	d2k.ubofci	EF980215.rdg	3/29/2000 QS	Pass
5c	d2k.ubofci	EF980215.rdg	3/29/2000 QS	Pass
5d	d2k.ubofci	EF980215.rdg	3/29/2000 QS	Pass
5e	d2k.ubofci	EF980215.rdg	3/29/2000 QS	Pass

Comments:

1. EF980215.rdg was run through d2k.ubofci three times. First, it was run through d2k.ubofci with output file name parameter set as "testrpt.txt". An output file named testrpt.txt was stored in the directory, */a1c/distributor ID/patient ID/ BICO Login ID* (testrpt.txt is now stored within the file testubci.txt). Then, it was run through d2k.ubofci with output file name parameter set as NULL, and an output file named evl_ddddpppppp.txt, where dddd is the distributor Id and pppppp the patient ID, was stored in above directory, too. The threshold in both runs was set as default (90), the test result was PASS. Finally, EF980215.rdg was run through d2k.ubofci with threshold set to 60. The test result was FAIL. These results were stored in testubci.txt.
2. Short.rdg was run through d2k.ubodci and a test report was generated in the above directory. It was also calculated by hand entry with a calculator. The mean and standard deviation of the absolute values of the difference between the paired HemoCue and D2000 measurements were computed. An upper boundary of a 95% confidence interval was computed and compared to a threshold of 90. The upper boundaries calculated by hand entry in a calculator and the d2k,ubofci were identical to 3 decimal places. The test results were the same, too. The difference occurred because the output of d2k.ubofci was rounded to 3 decimal places. The results was stored in tstshort.txt
3. Short.rdg was run through d2k.ubodci and the calculated upper boundary of a confidence interval was displayed on the screen.
4. Short.rdg was run through d2k.ubodci and a Pass or Fail test result was displayed on the screen.
5. EF980215.rdg was run through d2k.ubofci. A text file was created in the directory: */a1c/distributor ID/patient ID/BICO Login ID*. The file name might be intentionally named or automatically named as evl_ddddpppppp.txt, where dddd was the distributor ID and the pppppp was the user ID. The result was stored in testubci.txt.
    - Distributor ID was contained in the text file.
    - Patient ID was contained in the text file.
    - .rdg file name was contained in the text file.
    - The threshold used was contained in the text file.

- The upper boundary of a confidence interval was contained in the text file.
- The "Evaluation Status" (Pass or Fail) was contained in the text file.

Validation Plan Section: 4.3.3

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

1. Hand calculate the relative error between the average Diasensor 2000 and HemoCue readings, and compare to the output of the software. They should be identical.
2. Hand calculate the Standard Error and compare to the output of the software. They should be identical.
3. Confirm that the number of glucose readings is correct.
4. Confirm that the following are output to a file:
   - The relative error between the average Diasensor 2000 and HemoCue readings.
   - The Correlation Coefficient, Standard Error, Slope, Intercept, and the number of glucose readings.
   - A plot displaying the Diasensor 2000 vs. HemoCue individual readings.
5. Confirm that the output file is named according to the naming convention and is in the correct directory.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.report.plot	c6098.rdg, alltod.rdg	3/27/00, MP	P
2	d2k.report.plot	c6098.rdg	3/27/00, MP	P
3	d2k.report.plot	c6098.rdg, alltod.rdg	3/27/00, MP	P
4a	d2k.report.plot	c6098.rdg, alltod.rdg	3/27/00, MP	P
4b	d2k.report.plot	c6098.rdg	3/27/00, MP	P
4c	d2k.report.plot	c6098.rdg	3/27/00, MP	P
5	d2k.report.plot	c6098.rdg	3/28/00, MP	P

Comments:

1. C6098.rdg and alltod.rdg were run through d2k.report.plot. C6098.rdg only had the first 3 timecodes, but alltod.rdg had all 9 timecodes. The relative errors for all 3 timecodes in c6098.rdg were hand calculated, as were the relative errors for all 9 timecodes in alltod.rdg. All relative errors were found to be identical to their respective relative errors output by d2k.report.plot. The relative errors that were used can be found in the files rep103.txt and alltod.txt.
2. C6098.rdg was run through d2k.report.plot with the Standard Error being calculated by the program. Using this same data, the Standard Error was hand calculated. The Standard Errors were identical. The Standard Error used can be found in rep103.txt.
3. C6098.rdg was run through d2k.report.plot. The number of glucose readings was written to the file rep103.txt. Upon looking at valid readings in c6098.rdg and comparing this to the number of readings output by the program, the numbers were identical.
4. The relative error, Correlation Coefficient, Slope, Standard Error, Intercept and number of glucose readings were all written to the text file output by d2k.report.plot, while the plot of Diasensor versus HemoCue readings was output to a postscript file.
   a) The relative error was calculated for just the time codes in c6098.rdg. These were printed to the file rep103.txt. Then, to confirm that the program worked for all time codes, alltod.rdg was run through d2k.report.plot. The relative error for all time of day codes was written to the file alltod.txt.
   b) The Correlation Coefficient, Slope, Standard Error, Intercept and number of glucose readings were all written to rep103.txt, when c6098.rdg was run through d2k.report.plot.

c) The postscript file rep103.ps was out put from d2k.report.plot when c6098.rdg was run through the program. This file contains a plot of Diasensor reading versus HemoCue readings.

5. C6098.rdg was again run through d2k.report.plot. The output text file was written to the proper directory with the proper name. The file is rep_0101000103.txt

Validation Plan Section: 4.4.1

Software Used to Attach to the Correct Patient Directory

1. Confirm that the following parameters can be used, and that the software attaches to the correct directory based on the parameters.
   - Distributor ID, a parameter.
   - Patient ID, a parameter.
   - Subdirectory, an optional parameter defaulted to null. Test both null and "src" subdirectory.
   - Return directory, a parameter defaulted to "F". If the parameter is used as "T", do not attach to the directory, just return it to the calling program. Test both "T" and "F".
2. Confirm that, if there are multiple BICO login ID's for the Distributor ID/User ID combination, a list of the available BICO login ID's is displayed and the user is asked to choose one.

Item:	Program(s):	Data Used:	Date/Initials of Tester	Pass/Fail
1	d2k.dotdats	d2k.master.list	3/28/00, MP	P
1a	d2k.dotdats	d2k.master.list dist column	3/28/00, MP	P
1b	d2k.dotdats	d2k.master.list patid column	3/28/00, MP	P
1c	d2k.dotdats	d2k.master.list	3/28/00, MP	P
1d	d2k.dotdats, d2k.report.plot	d2k.master.list, c6098.rdg	3/28/00, MP	P
2	d2k.dotdats	d2k.master.list	3/28/00, MP	P

Comments:

1. The following parameters were run through d2k.dotdats, and the program was checked to be sure that it attaches to the correct directory based on the parameters. D2k.dotdats attached to the correct directory each time. The same top level directory was used throughout d2k.master.list. D2k.dotdats has also been used successfully over and over again in many of the other programs tested in the document for the following 4 parameters.
   a) D2k.master.list contained 2 distributor ID's with various patient ID's and login ID's. The same patient ID was assigned to both distributors to make sure there would be no confusion. The program had no problem finding the correct distributor ID.
   b) D2k.master.list contained various patient ID's. All were used in d2k.master.list to make sure the program would attach to the proper directory and that all numbers could be used. The program had no problem finding the correct patient ID.
   c) The program d2k.dotdats was run for each patient in d2k.master.list. First the parameter was set to null, and the program correctly attached to each login directory for each distributor/patient combination. Then the parameter was set to "src", and the program correctly attached to each src directory for each distributor/patient/login combination.

d) The return parameter was set to false for all of the above testing, and the program successfully attached to the proper directories. In d2k.report.plot, the return parameter was set to true and the program successfully wrote the specified file to the specified directory.

2. A Distributor ID/User ID combination was made in d2k.master.list, which had multiple BICO login ID's. A list of the available BICO login ID's was displayed and the user was asked to choose one. Each of the different BICO login ID's was selected, and each time the proper directory was attached. This was done with the path parameter set to both null and "src".

Conclusions

The Patient Data Analysis software functions within all specified parameters and should be released.

Suggestions for Further Work

The Preliminary Plots, in section 4.2.2 of the PDA Software Validation Plan, are not absolutely necessary for the Calibration process. They have not been completed yet, and therefore have not been tested. Test the plots when complete.