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BIOCONTROL
TECHNOLOGY INC.

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Rev. AA

Diasensor 2000 Calibration
Product Use Procedure

1. Scope

This document defines the procedure for collecting Calibration Data, the criteria to determine if the collection of Calibration Data is complete, the procedure for processing the Calibration Data, and the criteria to judge the success of the Calibration.

2. References

32000-PD02	*Diasensor 2000* Algorithm, Product Specification
32000-PU01	*Diasensor 2000* Data Acquisition, Product Use Procedure
31259-PU01	*Diasensor 2000* Patient Data Analysis, Product Use Procedure
31170-ML01	*Diasensor 2000* User's Guide
Vendor Supplied	*HemoCue* Operating Manual

3. Definition of Terms

3.1 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.

3.2 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.

3.3 Calibration Data

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

3.4 Calibration Session

A calibration session (C-session) consists of four (4) subsessions indexed over four (4) index positions.

3.5 Calibration Sitting

A calibration sitting consists of the following nominal sequence of measurements: C-session -- C-session -- C-session -- *HemoCue* reading-- C-session -- C-session -- C-session. Under normal circumstances, the duration of a calibration sitting is approximately fifteen (15) minutes.

3.6 Coarse Outlier

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

3.7 Countable Calibration Session

Session that is valid and with at least one valid subsession that did not fail the standard deviation check. See the *Diasensor 2000* Algorithm Specification for a complete description of the standard deviation check.

3.8 Countable Calibration Sitting

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

3.9 Evaluation

The collection of the Evaluation Data, the application of the glucose measurement algorithm under defined and controlled conditions, and a determination that the patient's calibration coefficients meet acceptance criteria so the patient may use the *Diasensor 2000* for glucose measurement.

3.10 Evaluation Data

The *Diasensor 2000*'s glucose readings and/or error codes and the corresponding *HemoCue* monitor's glucose readings collected for the purpose of verifying a patient's calibration coefficients.

3.11 HemoCue

An FDA approved invasive blood glucose monitor produced by the *HemoCue* Corporation.

3.12 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.

3.13 Indexing

Refers to the handgrip position of the *Diasensor 2000* arm tray. The user is instructed to move the grip into four (4) different positions that are $^1/_2$ inch apart for one and one half ($1^1/_2$) inches of total travel.

3.14 Measurement

The application of the glucose measurement algorithm under normal user conditions and quality monitoring procedures to obtain a glucose reading. The *Diasensor 2000* readings are reported to the diabetic patient's attending physician for determination of adjustments to the patient's diet and/or insulin regimen.

3.15 Measurement Algorithm

The glucose measurement algorithm uses the patient's calibration coefficients extracted from Calibration Data to transform the *Diasensor 2000* spectral and sensor readings into a measurement of the patient's glucose.

3.16 Reference Ratio Check

Performed by the *Diasensor 2000* embedded software to detect a dirty optical probe. If it detects this condition, the *Diasensor 2000* rejects the entire session and displays *"Problem Detected"* on the screen. The patient must repeat the session. See the *Diasensor 2000* Algorithm Specification for more details.

3.17 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.

3.18 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.

3.19 Skin Level Threshold Check

Performed by the *Diasensor 2000* embedded software to detect when the arm is inadvertently lifted from the optical probe during data collection. If it detects this event, the *Diasensor 2000* rejects the entire session and displays an error code indicating what occurred on the screen. The patient must repeat the session. See the *Diasensor 2000* Algorithm Specification for more details.

3.20 Subsession

One session may consist of several subsessions. A subsession is the series of events starting from placement of the arm on the arm tray and ending with removal of the arm, breaking optical contact between the arm and the probe. From a data acquisition point of view, a subsession is the time during which the *Diasensor 2000* collects sixteen (16) individual spectra, each preceded by a single dither. See the *Diasensor 2000* Data Acquisition Procedure for more details of session and subsession definitions.

3.21 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.

3.22 Valid Subsession

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

4. Safety Precautions

- Instruct patients to strictly follow instructions in the *Diasensor 2000* User's Guide and the *HemoCue* Operating Manual.

5. Equipment and Material

- *Diasensor 2000*
- Access to a telephone jack
- PCMCIA User Card, version for Calibration
- *HemoCue* glucose monitor with supplies
- *HemoCue* Operating Manual
- *Diasensor 2000* User's Guide

6. Procedure

6.1 Calibration Data Collection

1. Customer support arranges delivery of the required equipment and material to the patient's home. Please see the *Diasensor 2000* User's Guide for device placement considerations.

2. Customer support advises the patient in use of the *Diasensor 2000* and the *HemoCue* monitor.

3. Nominal duration of Calibration Data Collection is sixty (60) days.

4. The patient performs at least two (2) calibration sittings each day, preferably one at a morning fasting state and one at a patient selected evening time slot, either before dinner or at bedtime. Additional sittings are beneficial and encouraged if started at least one (1) hour after the patient's most recent meal. Advise the patient that additional sittings are especially encouraged during times of either low (less than 150 mg/dL or 8.3 mmol/L) or high (greater than 300 mg/dL or 16.7 mmol/L) blood glucose concentration.

5. The Calibration data is transferred via the Internet from the *Diasensor 2000* to Biocontrol Technology, Inc.

6. See the *Diasensor 2000* Data Acquisition and *Diasensor 2000* Patient Data Analysis Procedures for more details of Calibration Data Collection.

6.2 Sufficient Calibration Data Criteria

The Calibration Data Collection time period must meet the following criteria to be sufficient to extract a valid set of calibration coefficients. If it does not meet any one of the following criteria, ask the patient to continue Calibration Data Collection.

1. Number of days with at least one (1) countable calibration sitting must be greater than or equal to fifty-four (54).

2. Number of countable calibration sittings must be greater than or equal to 108.

3. Number of countable calibration sessions must be greater than or equal to 600.

4. See the *Diasensor 2000* Patient Data Analysis Procedure for the details of checking for sufficient data.

6.3 Goodness of Calibration Data Criteria

The Calibration Data must meet the following criteria to be a successful calibration and ensure the patient has a reasonable chance to satisfy the Evaluation criteria. If the Calibration Data does not satisfy any one of the following criteria, the patient returns the instrument and is told that he/she cannot be calibrated.

1. *HemoCue* standard deviation is greater than or equal to 40 mg/dL.
2. Percent of subsessions that fail the standard deviation check is less than or equal to 30% of the total valid subsessions.
3. The calibration correlation coefficient on subsession absorbance spectra, using rank 53, is greater than or equal to 0.7.
4. See the *Diasensor 2000* Patient Data Analysis Procedure for the details of checking the goodness of data criteria. Also, see the *Diasensor 2000* Algorithm Specification for the details of the standard deviation check.

6.4 Calibration Data Processing

The Patient Data Analysis Section of Computational Analysis performs all Calibration Data processing. Use pixel numbers 1 to 57 as the wavelength range.

See the Calibration section of the *Diasensor 2000* Patient Data Analysis Procedure for a complete description of Calibration Data processing.