SAVE REQUEST

USER: (ldt)
FOLDER: K032482 - 213 pages
COMPANY: STANBIO LABORATORY (STANLABO)
PRODUCT: SYSTEM, HEMOGLOBIN, AUTOMATED (GKR)
SUMMARY: Product: STANBIO LABORATORY HEMOPOINT H2 HEMOGLOBIN MEASUREMENT SYSTEM

DATE REQUESTED: Oct 8, 2014
DATE PRINTED: Oct 8, 2014

Note: Printed
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

Trade Name: HemoPoint® H2 Hemoglobin Measurement System

Common/Classification Name: Automated Hemoglobin System

Device Classification: Class: II
CFR: 21 CFR 864.5620
Product Code: GKR

Manufacturer: Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

The recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyannmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN₃ and thus was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti's method is also known as the azide methemoglobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

In the HemoPoint® H2, however, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled cuvette is inserted into the HemoPoint® H2 photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb level is calculated and displayed.

In the HemoPoint® H2 photometer the light transmitted through the cuvette sample is measured.

Principle of photometric transmitted light measurement.

\[ P_0: 100\% \text{ - light intensity, } P: \text{ remaining light intensity, } b: \text{ distance through the solution} \]

For this purpose, light is directed through the blood sample and the transmission T is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using Lambert-Beers Law.

Light emitting diodes (LED's) are used as light sources and a photodiode to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).
### Intended Use:

The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/L or 12.0 to 18.0 g/dl). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values and will not be reported.

For In Vitro Diagnostic Use Only

### Comparison To Predicate Device:

#### Precision:

Within-run imprecision HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue Device $\leq 2\%$

<table>
<thead>
<tr>
<th>Hemoglobin/high (17.3 g/dL)</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EP5-A):</td>
<td>$S_w 0.111$ g/dL, CV 0.6 %</td>
<td>$S_w 0.103$ g/dL, CV 0.6 %</td>
</tr>
<tr>
<td>Total Precision (NCCLS EP5-A):</td>
<td>$S_T 0.207$ g/dL, CV 1.2 %</td>
<td>$S_T 0.162$ g/dL, CV 0.9 %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin/low (10.7 g/dL)</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EP5-A):</td>
<td>$S_w 0.095$ g/dL, CV 0.9 %</td>
<td>$S_w 0.068$ g/dL, CV 0.6 %</td>
</tr>
<tr>
<td>Total Precision (NCCLS EP5-A):</td>
<td>$S_T 0.114$ g/dL, CV 1.1 %</td>
<td>$S_T 0.086$ g/dL, CV 0.8 %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin/normal (12.9 g/dL)</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EP5-A):</td>
<td>$S_w 0.084$ g/dL, CV 0.7 %</td>
<td>$S_w 0.102$ g/dL, CV 0.8 %</td>
</tr>
<tr>
<td>Total Precision (NCCLS EP5-A):</td>
<td>$S_T 0.148$ g/dL, CV 1.1 %</td>
<td>$S_T 0.134$ g/dL, CV 1.0 %</td>
</tr>
</tbody>
</table>

**Between-Day Imprecision**

Single observation, 20 days

<table>
<thead>
<tr>
<th>Hemoglobin/hour (17.3 g/dL):</th>
<th>Mean ± SD (g/dL), CV (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.7 g/dL:</td>
<td>10.9 ± 0.122, CV 1.2 %</td>
</tr>
<tr>
<td>12.9 g/dL:</td>
<td>13.0 ± 0.141, CV 1.1 %</td>
</tr>
<tr>
<td>17.3 g/dL:</td>
<td>17.2 ± 0.169, CV 1.0 %</td>
</tr>
</tbody>
</table>

**Correlation Study:**

Correlation coefficient HemoPoint® H2 System compared to NCCLS H15-A3 reference method, venous blood: $\geq 0.98$

Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to HemoCue System, venous blood: $\geq 0.97$

2 - 3
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT’D

Experimental Data:

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

| Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood (Summary from 4 Clinical Study Sites) | - Y= 0.023 + 1.006X  
- R=0.999  
- N=174, duplicate measurements  
- Range 3.31 g/dL to 24.4 g/dL |
| Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites) | - Y=- 0.233 +1.001X  
- R=0.998  
- N=286, duplicate measurements  
- Range 3.25 g/dL to 23.85 g/dL |

HemoPoint® H2 cuvettes measured in HemoCue device:

| Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites) | - Y= 0.139 +986X  
- R=0.999  
- N=286, duplicate measurements  
- Range 3.25 g/dL to 23.85 g/dL |

Comparison to Predicate Device:

<table>
<thead>
<tr>
<th>Specification</th>
<th>HemoPoint® H2</th>
<th>HemoCue</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument</td>
<td>No. 1</td>
<td>No. 2</td>
<td>No. 1 ↔ No. 2</td>
</tr>
<tr>
<td>Measurement range</td>
<td>0 – 25.6 g/dL</td>
<td>0 – 25.6 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Specified range</td>
<td>0 – 25.6 g/dL</td>
<td>0 – 23.5 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Specified accuracy</td>
<td>± 0.3 g/dL at =14 g/dL</td>
<td>± 0.3 g/dL at =14 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Sample material</td>
<td>venous, arterial or capillary human blood</td>
<td>venous, arterial or capillary human blood</td>
<td>equivalent</td>
</tr>
<tr>
<td>Measuring time</td>
<td>Approximately 30 – 60 sec</td>
<td>Approximately 30 – 60 sec</td>
<td>measuring time depends on the concentration</td>
</tr>
<tr>
<td>Measuring units</td>
<td>mol/L, g/dL, g/L</td>
<td>mol/L, g/dL, g/L</td>
<td>equivalent</td>
</tr>
<tr>
<td>Calibration</td>
<td>against NCCLS reference method</td>
<td>against ICSH reference method</td>
<td>NCCLS is current version of the method</td>
</tr>
<tr>
<td>Method</td>
<td>Azidemethemoglobin method (Vanzetti)</td>
<td>Azidemethemoglobin method (Vanzetti)</td>
<td>equivalent</td>
</tr>
</tbody>
</table>

Conclusion / Substantial Equivalence:
The HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes and the predicate devices, HemoCue B-Hemoglobin System with microcuvette are substantially equivalent based on design and function.

Kirk Johnson  
QA/Regulatory Affairs Manager  
Stanbio Laboratory

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Re:  k032482
Trade/Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System
Regulation Number: 21 CFR § 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: II
Product Code: GKR
Dated: August 5, 2003
Received: August 12, 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Indications for use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.
Date: 6/4/04

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K032482/A061

To: Division Director: HEOLVD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO PD.

Additional information requires a new 510(k); however, the information submitted is incomplete. (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440).

Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be reviewed by the DMC within 10 working days from the date of this memorandum.

Reviewed by: 

Date: 3/7/05

Draft #2: 9/8/99
Draft #3: 1/3/00
Draft #4: 3/7/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
June 3, 2004

Document Mail Center
HFZ-401
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850
Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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Sincerely yours,

Steven I. Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Number (if known): 1032482

Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications for use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) 1032482

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR. Over the Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Principles of the Procedure
In the HemoPoint® H2 system, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled microcuvette is inserted into the HemoPoint® H2 photometer; the color produced by the chemical reaction in the cuvette is measured, and the hemoglobin level is calculated and displayed. For this purpose, light is directed through the blood sample and the absorption is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using the Beer’s-Lambert Law. Light emitting diodes (LED’s) are used as light sources and a photodiode is used to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

The Microcuvette
The plastic microcuvette consists of a clear body with a cavity which takes up approximately 10 µL of blood which combines with the reagent. The optical distance between the cuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples.

The Chemistry Principle
In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary: sodium deoxycholate dissolves and disperses the cell walls of the red blood corpuscles. Hence the hemoglobin formerly contained in the erythrocytes is now available free in the plasma. The bivalent iron of the oxymyoglobin and the deoxymyoglobin becomes oxidized by sodium nitrite (NaNO2) to trivalent iron, in methemoglobin. Existing and formed methemoglobin and azide ions from sodium azide (NaN3) form a colored complex which exhibits maximal absorption at 540 and 575 nm and hence it can be quantitatively determined photometrically.

Reagents
HemoPoint® H2 Microcuvettes, Cat. No. 3011
40% w/w sodium deoxycholate, 20% sodium azide, 20% w/w sodium nitrite and 20% w/w non-reactive ingredients.

Warnings and Precautions
Microcuvettes are designed for in-vitro diagnostic use only.

2. Mix the sample tube well (i.e. by a mechanical rotator or hand inversion at least 10 times).

Procedure
Refer to the HemoPoint® H2 User’s Guide (or manual of the HemoCue® instrument) for proper use of the photometer.

Materials Provided
HemoPoint® H2 Microcuvettes, Cat.No. 3010-050

Materials Required But Not Provided
HemoPoint® H2 or HemoCue® Photometer
HemoPoint® H2 Control Cuvette
Disposable pipettes (venous or arterial blood only)
Plastic film (venous or arterial blood only)
Lint-free material

Instructions For Use (Capillary)
1. Make sure that the photometer is ready for use. See the HemoPoint® H2 User’s Guide or HemoCue® Operating Manual for the device.
2. Make sure that your patient is sitting comfortably.
3. There should be a good blood circulation in the hand from which you wish to take blood, e.g. it should be warm and relaxed.
4. Lightly massage the fingers, in order to stimulate circulation.
5. Disinfect the puncture site and allow to dry.
6. Take out a microcuvette from the container and close the lid immediately.
7. Press lightly on the fingertip and puncture with a suitable sampling device on the side of the fingertip.
8. Blot away the first drop of blood then, if necessary, press gently once again to get a 2nd drop of blood which is large enough to fill the microcuvette completely. Avoid “milking” the finger.
9. Hold the tip of the microcuvette tip in the middle of the drop of blood and let the cavity fill in one step. In case of air bubbles in the optical eye, discard the microcuvette and take another sample using a new microcuvette.

Measurement light must pass through the sample cuvette to the photo detector with the least possible interference. It is therefore crucial not to touch the optical eye of the cuvette with fingers, dirty or sharp objects.
10. In order to avoid contamination of the cuvette holder, remove surplus blood from the outside of the microcuvette. 11. The microcuvette sample prepared in this way can now be measured immediately or within 10 minutes at the latest.

Instructions For Use (Venous or Arterial)

1. Make sure that the Photometer is ready for use. See the HemoPoint® H2 User’s Guide or HemoCue® Operating Manual for the device.
2. Remove sample tube from the refrigerator and bring it to room temperature.
3. Mix the sample tube well (i.e. by a mechanical rotator or mixing by hand at least 10 times).
4. Take out a microcuvette from the container and close the lid immediately.
5. Pipette a sufficient drop of blood on a non-absorbent material (i.e. plastic film).
6. Hold the tip of the microcuvette in the middle of the drop of blood and let the cavity fill in one step. In case of air bubbles in the optical eye, discard the microcuvette and take another sample using a new microcuvette.
7. In order to avoid contamination of the cuvette holder, remove surplus blood from the outside of the microcuvette.
8. The cuvette sample prepared in this way can now be measured immediately or within 10 minutes at the latest.

Limitations of the Procedure

1. The microcuvette sample can be measured immediately or within 10 minutes at the latest, otherwise false results may be obtained.
2. Air bubbles in the optical eye, caused by inadequate filling of the microcuvette cavity, may cause false results. Discard the microcuvette and take another sample using a new microcuvette.
3. Ensure that you do not hold the microcuvette at its filling end, because this may contaminate the optical eye.
4. In order to avoid contamination of the cuvette holder, remove surplus blood from the outside of the microcuvette.
5. All results above 23.5 g/dL or equivalent must be confirmed by laboratory methods.
6. Sulfhemoglobin is not measured by this method. Carboxyhemoglobin and turbidity due to leukocytosis or hyperlipemia do not interfere.

Expected Values

The following hemoglobin values are considered normal:

<table>
<thead>
<tr>
<th>Age</th>
<th>Hemoglobin (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>13.0 - 18.0</td>
</tr>
<tr>
<td>Adult females</td>
<td>11.0 - 16.0</td>
</tr>
<tr>
<td>Children</td>
<td>11.0 - 16.0</td>
</tr>
<tr>
<td>Infants (postnatal)</td>
<td>10.0 - 14.0</td>
</tr>
</tbody>
</table>

Due to a wide range of conditions which affect normal values, it is recommended that each laboratory establish its own "normal" range.

Quality Control

The control cuvette must be read each day of testing using the appropriate control cuvette provided with the photometer. Good Laboratory Practices recommend the daily use of external controls to assure that the microcuvettes and the photometer are performing correctly. For this purpose, we recommend the use of Stanbio’s HemoPoint® Hemoglobin Controls, Cat.No.3000-681. Do not use Cyanmethemoglobin standards with this test.

Results

The test result is displayed directly on the screen of the HemoPoint® H2 or the HemoCue® photometer. No calculations are necessary. The test is linear up to 23.5 g/dL.

Performance Characteristics

Precision

Within-run precision using the HemoPoint® H2 and the HemoCue® devices with the HemoPoint® H2 microcuvettes is 2%. The precision evaluation was carried out in accordance with NCCLS EP5-A. On each of 20 testing days, two separate runs with duplicate measurements within each run were carried out. Three commercially available control materials were used. The test was carried out using (6) HemoPoint® H2 devices; (2) HemoCue® devices; (16) lots of HemoPoint® H2 microcuvettes and (3) operators.

Correlation

Correlation coefficient of the HemoPoint® H2 System compared to the NCCLS H15-A3 reference method. Venous blood: r = 0.98

Correlation coefficient of the HemoPoint® H2 microcuvettes on the HemoCue® device compared to HemoCue® System. Venous blood: r = 0.97

References

3. HemoPoint® H2 Hemoglobin testing system User’s Guide, Stanbio Laboratory, Boerne, Texas USA.

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood

1. Y = 0.923 x + 0.064
2. R² = 0.999
3. N = 14, duplicate measurements
4. Range 3.11 g/dL to 24.4 g/dL
5. Summary of results from (4) Clinical Sites

HemoPoint® H2 microcuvettes measured in HemoCue® device:

Regression line and correlation coefficients compared to HemoCue® system (g/dL), venous blood

1. Y = 0.223 x + 0.001
2. H = 0.595
3. N = 298, duplicate measurements
4. Range 3.25 g/dL to 23.85 g/dL
5. Summary of results from (4) Clinical Sites

Expected Values

5. All results above 23.5 g/dL or equivalent must be confirmed by laboratory method.
6. Sulfhemoglobin is not measured by this method. Carboxyhemoglobin and turbidity due to leukocytosis or hyperlipemia do not interfere.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Mr. Kirk Johnson  
QA/Regulatory Affairs Manager  
Stanbio Laboratory  
1261 North Main Street  
Boerne, Texas, 78006

Re: k032482/A003  
Test System: HemoPoint®  
Dated: September 17, 2004  
Received: September 20, 2004

Dear Mr. Johnson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your waiver application under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) [42 USC 263(a)]. We regret to inform you that your request for modification of your current waiver to include the use of Stanbio’s HemaPoint® H2 cuvettes on the HemoCue® does not qualify for a waiver modification.

FDA has determined that your modification does not meet the criteria for a waived test for a waived instrument.

If you have any questions about this letter, please contact Robert Becker, Jr., M.D., Ph.D. at 240-276-0493 ext. 212.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health
Date: 9/20/04
From: DMC (HFZ-401)
Subject: Premarket Notification Number(s): KC32482/A3
To: Division Director: HE/CVD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

- Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

- Additional information requires a new 510(k); however, the information submitted is incomplete. (Notify company to submit a new 510(k).[Prepare the K30 Letter on the LAN]

- No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

**CLIA CATEGORIZATION** refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

- Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

- Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

- No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: [Signature]

Date: [Signature] 3/7/05

Draft #2: 9/8/99
Draft #3: 1/3/00
Draft #4: 3/7/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
September 17, 2004

Document Mail Center
HFZ-401
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850
Sincerely,

Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory
Categorization Notification Waived

Regulations codified at 42 CFR 493.15 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test systems or assay for the analyte is categorized below:

Test System: STANBIO HEMOGLOBIN ANALYZER
Analyte: HEMOGLOBIN
Complexity: Waived
510K or PMA Number: K032482

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for evaluation of waiver.

This complexity categorization is effective as of the date of this notification. This categorization will be reported on FDA's home page http://www.fda.gov/cdrh/clia. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. This categorization will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice. For questions regarding FDA's categorization procedure, contact Clara A. Sliva, Acting CLIA Coordinator, at (301)827-0496 or email at CLIA@CDRH.FDA.GOV

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications for use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.
**HemoPoint® H2 Microcuvettes**

**Procedure No. 3010**

For the quantitative determination of hemoglobin in capillary, venous or arterial whole blood.

**CLIA Complexity: Waived**

**Intended Use**

The HemoPoint® H2 microcuvettes are intended to be used in the HemoPoint® H2 Photometer and the HemoCue® B-Hemoglobin Photometer. The reagents/microcuvettes and the photometer form an analytical system.

**Summary and Principle**

The HemoPoint® H2 system is intended to be used for the quantitative determination of hemoglobin (Hgb) concentration in human blood. It consists of a photometer instrument and individual single-use microcuvettes filled with reagents. Using the microcuvette, a small amount of capillary, venous or arterial blood is taken up by capillary action. The microcuvettes are intended to be used once only and must be disposed of after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment. The HemoPoint® H2 system is designed for use in medical practices and in clinical laboratories to assist in medical diagnostics. In addition it can be used in emergency and intensive care units and in medical facilities such as blood donor sessions and blood banks.

Blood sampling and operating the HemoPoint® H2 system should be carried out by trained personnel with sound knowledge of the system. HemoPoint® H2 cuvettes can also be used in combination with the HemoCue® photometer.

The recognized reference method for total hemoglobin is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolyzed and the bivalent iron in oxyhemoglobin and deoxyhemoglobin are oxidized by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the Hgb concentration. In 1966, Vanzetti suggested to replace KCN by NaN₃ and thus he was able to reduce the toxicity of the reagent mixture considerably. Vanzetti's method is also known as the azide methemoglobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

**Principles of the Procedure**

In the HemoPoint® H2 system, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled microcuvette is inserted into the HemoPoint® H2 photometer, the color produced by the chemical reaction in the cuvette is measured, and the hemoglobin level is calculated and displayed.

For this purpose, light is directed through the blood sample and the absorption is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using the Beer's-Lambert Law. Light emitting diodes (LED's) are used as light sources and a photodiode is used to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

**The Microcuvette**

The plastic microcuvette consists of a clear body with a cavity which takes up approximately 10 μL of blood which combines with the dry reagent chemistry. The optical distance between the cuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples.

**The Chemistry Principle**

In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary: sodium deoxycholate dissolves and disperses the cell walls of the erythrocytes, the glycerol is available free in the solution. The bivalent iron of the oxyhemoglobin and the deoxyhemoglobin becomes oxidized by sodium nitrite NaNO₂ to trivalent iron, in methemoglobin. Existing and formed methemoglobin and azide ion initial sodium azide Na₃[54] form a colored complex which exhibits maximal absorption at 540 and 575 nm and hence it can be quantitatively determined photometrically.

**Reagents**

HemoPoint® H2 Microcuvettes, Cat. No. 3011

- 40% w/v sodium deoxycholate, 20% sodium azide, 20% w/v sodium nitrite and 27% w/v non-reactive ingredients.

**Warnings and Precautions**

Microcuvettes are designed for in-vitro diagnostic use only. The reagents which coat the inner walls of the microcuvettes are harmful and must not be swallowed. Wear suitable protective (gloves) at all times when handling blood samples. Please note that all human blood samples or products must be handled as potential infectious waste per your local regulations.

**Storage**

HemoPoint® H2 microcuvettes are to be stored solely in the original container and at room temperature 59 - 86°F (15 - 30°C). DO NOT refrigerate! Use cuvettes within 3 months after opening container. Document the initial opening date on the container label in the space provided. Only remove one microcuvette at a time from the container and immediately close the lid. The microcuvettes are analyzed immediately upon insertion into the HemoPoint® H2 photometer.

**Sample Collection and Preparation**

The HemoPoint® H2 Photometer can be used with capillary, venous, or arterial blood. Use EDTA, heparin or heparin/fluoride as anticoagulants, preferably in solid form, to avoid dilutional effects. Venous and arterial blood samples may be used if the blood collected is not more than 24 hours old and the samples have been stored refrigerated 35 - 46°F (2-8°C). Prepare stored samples for measurement as follows:

1. Remove sample tube from the refrigerator and bring it to room temperature.
2. Mix the sample tube well. (i.e. by a mechanical rotator or hand inversion at least 10 times).

**Procedure**

Refer to the HemoPoint® H2 User's Guide (or manual of the HemoCue® instrument) for proper use of the photometer.

**Materials Provided**

HemoPoint® H2 Microcuvettes, Cat. No. 3010-050

**Materials Required But Not Provided**

- HemoPoint® H2 or HemoCue® Photometer
- HemoPoint® H2 or HemoCue® Control Cuvette
- HemoPoint® H2 Hemoglobin Controls, (Cat. No. 3060-601)
- Disposable pipettes (venous or arterial blood only)
- Plastic film (venous or arterial blood only)
- Lint-free material

**Instructions For Use (Capillary)**

1. Make sure that the Photometer is ready for use. See the HemoPoint® H2 User's Guide or HemoCue® Operating Manual for the device.
2. Make sure that your patient is sitting comfortably.
3. There should be a good blood circulation in the hand from which you wish to take blood, e.g., it should be warm and relaxed.
4. Lightly massage the fingers, in order to stimulate circulation.
5. Disinfect the puncture site and allow to dry.
6. Take out a microcuvette from the container and close the lid immediately.
7. Press lightly on the fingertip and puncture with a suitable sampling device on the side of the fingertip.
8. Blot away the first drop of blood then, if necessary, press gently once again to get a 2nd drop of blood which is large enough to fill the microcuvette completely. Avoid "milking" the finger.
9. Hold the tip of the microcuvette tip in the middle of the drop of blood and let the cuff in one step. In case of air bubbles in the optical eye, discard the microcuvette and take another sample using a new microcuvette.
10. In order to avoid contamination of the cuvette holder,
Quality Control
The HemoPoint® H2 AutoCheck performs an internal check of the photometer's optic system every time the cuvette holder is opened. If additional regulatory quality control checks are required, the following checks are recommended. (1) The control cuvette supplied with the photometer can be used for a simple check of the photometer's calibration. (2) Good Laboratory Practices recommend the daily use of external controls to assure that the microcuvettes and the photometer are performing correctly. For this purpose, we recommend the use of Stanbio's HemoPoint® H2 Hemoglobin Controls, Cat. No. 3000-601. Do not use cyanmethemoglobin standards with this test.

Use of HemoPoint® H2 Cuvettes on HemoCue® Analyzer
To ensure correct performance, validation of HemoCue® Analyzer with the HemoPoint® H2 cuvettes is required initially and each time the instrument is serviced or its software is upgraded. This validation is accomplished using the Stanbio HemoPoint® H2 Hemoglobin Controls. The controls are tested on the instrument and the obtained values must be within the established ranges. If values are outside the ranges, contact Stanbio's Technical Service.

Results
The test result is displayed directly on the screen of the HemoPoint® H2 or the HemoCue® photometer. No calculations are necessary. The test is linear up to 23.5 g/dL.

Performance Characteristics
Precision
Within-run precision using the HemoPoint® H2 and the HemoCue® devices with the HemoPoint® H2 microcuvettes is 2%. The precision evaluation was carried out in accordance with NCCLS EP5-A1. On each of 20 testing days, two separate runs with duplicate measurements were carried out. Three commercially available control materials were tested. The test was carried out using: (6) HemoPoint® H2 devices; (2) HemoCue® devices; (16) lots of HemoPoint® H2 microcuvettes and 3 operators.

Correlation
Correlation coefficient of the HemoPoint® H2 System compared to the NCCLS H15-A3 reference method. Venous blood: r = 0.98
Correlation coefficient of the HemoPoint® H2 microcuvettes on the HemoCue® device compared to HemoCue® System. Venous blood: r = 0.97

Expected Values

The following hemoglobin values are considered normal:

- Adult males: 13.0 – 18.0 g/dL
- Adult females: 11.0 – 16.0 g/dL
- Children: 11.0 – 16.0 g/dL
- Infants (postnatal): 10.0 – 14.0 g/dL

Due to a wide range of conditions which affect normal values, it is recommended that each laboratory establish its own “normal” range.

References
3. HemoPoint® H2 Hemoglobin testing system User's Guide, Stanbio Laboratory, Boerne, Texas USA.

HemoPoint® is a registered trademark of HemoPoint AB, Angelholm, Sweden.

For Technical Service call: 800-531-5535 or (800) 249-0772
Fax (830) 249-0851 e-mail: stanbio@stanbio.com
http://www.stanbio.com
Stanbio Laboratory #1261 North Main Street • Boerne, Texas 78006
DIN: RBB.3010.02 • Last Revision: 07/04 • Procedure No. 3010
September 17, 2004

Document Mail Center
HFZ-401
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850
Sincerely,

Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory
Categorization Notification Waived

Regulations codified at 42 CFR 493.15 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test systems or assay for the analyte is categorized below:

Test System: STANBIO HEMOGLOBIN ANALYZER
Analyte : HEMOGLOBIN
Complexity : Waived
510K or PMA Number : K032482

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for evaluation of waiver.

This complexity categorization is effective as of the date of this notification. This categorization will be reported on FDA's home page http://www.fda.gov/cdrh/clia. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. This categorization will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice. For questions regarding FDA's categorization procedure, contact Clara A. Sliva, Acting CLIA Coordinator, at (301)827-0496 or email at CLIA@CDRH.FDA.GOV

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known): \textbf{K 032482}

Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications for use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

\begin{center}
\textit{Josephine Burtelli
Division Sign-Off}
\end{center}

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) \textbf{K 032482}

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\begin{center}
\textit{Concurrence of CDRH, Office of Device Evaluation (ODE)}
\end{center}

Prescription Use \checkmark OR. Over the Counter Use

(Per 21 CFR801.109) (Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
HemoPoint® H2 Microcuvettes
Procedure No. 3010

For the quantitative determination of hemoglobin in capillary, venous or arterial whole blood.

CLIA Complexity: Waived

Intended Use
The HemoPoint® H2 microcuvettes are intended to be used in the HemoPoint® H2 Photometer and the HemoCue® B-Hemoglobin Photometer. The reagents/microcuvettes and the photometer form an analytical system.

Summary and Principle
The HemoPoint® H2 system is intended to be used for the quantitative determination of hemoglobin (Hgb) concentration in human blood. It consists of a photometer instrument and individual single-use microcuvettes filled with reagents. Using the microcuvette, a small amount of capillary, venous or arterial blood is taken up by capillary action. The microcuvettes are intended to be used once only and must be disposed of after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment. The HemoPoint® H2 system is designed for use in medical practices and in clinical laboratories to assist in medical diagnostics. In addition, it can be used in emergency and intensive care units and in medical facilities such as blood donor sessions and blood banks. Blood sampling and operating the HemoPoint® H2 system should be carried out by trained personnel with sound knowledge of the system. HemoPoint® H2 cuvettes can also be used in combination with the HemoCue® photometer.

The recognized reference method for total hemoglobin is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxyhemoglobin and deoxyhemoglobin is oxidized by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the Hgb concentration. In 1966, Vanzetti suggested to replace KCN by NaNO₂ and thus he was able to reduce the toxicity of the reagent mixture considerably. Vanzetti’s method is also known as the azide methemoglobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

Complexity: Waived

Principles of the Procedure
In the HemoPoint® H2 system, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled microcuvette is inserted into the HemoPoint® H2 photometer, the color produced by the chemical reaction in the cuvette is measured, and the hemoglobin level is calculated and displayed.

For this purpose, light is directed through the blood sample and the amount of light absorbed by the sample is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using the Beer-Lambert Law. Light emitting diodes (LED’s) are used as light sources and a photodiode is used to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

The Microcuvette
The plastic microcuvette consists of a clear body with a cavity which takes up approximately 10 µL of blood which combines with the dry reagent chemistry. The optical distance between the cuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples.

The Chemistry Principle
In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary: sodium deoxycholate dissolves and disperses the cell walls of the red blood corpuscles. Hence the hemoglobin formerly contained in the erythrocytes is now available free in the solution. The bivalent iron of the oxyhemoglobin and the deoxyhemoglobin becomes oxidized by sodium nitrite NaNO₂ to trivalent iron, in methemoglobin. Existing and formed methemoglobin and azide ions from sodium azide NaNO₃ form a colored complex which exhibits maximal absorption at 540 and 575 nm and hence it can be quantitatively determined photometrically.

Reagents
HemoPoint® H2 Microcuvettes, Cat. No. 3011
40% w/w sodium deoxycholate, 20% sodium azide, 20% w/w sodium nitrite and 20% w/w non-reactive ingredients.

Warnings and Precautions
Microcuvettes are designed for in-vitro diagnostic use only. The reagents which coat the inner walls of the microcuvettes are harmful and must not be swallowed. Wear suitable protective clothing (gloves) at all times when handling blood samples. Please note that all human blood samples or products must be handled as potential infectious waste per your local regulations.

Storage
HemoPoint® H2 microcuvettes are to be stored solely in the original container and at room temperature 59-86°F (15-30°C). DO NOT refrigerate! Use cuvettes within 3 months after opening container. Document the initial opening date on the container label in the space provided. Only remove one microcuvette at a time from the container and then immediately close the lid. The microcuvettes are analyzed optically in the HemoPoint® H2 photometer.

Sample Collection and Preparation
The HemoPoint® H2 Photometer can be used with capillary, venous, or arterial blood. Use EDTA, heparin or heparin/fluoride as anticoagulants, preferably in solid form, to avoid dilutional effects. Venous and arterial blood samples may be used if the blood collected is not more than 24 hours old and the samples have been stored refrigerated 35-46°F (2-8°C).

Prepare stored samples for measurement as follows:
1) Remove sample tube from the refrigerator and bring it to room temperature.
2) Mix the sample tube well. (i.e. by a mechanical rotator or hand inversion at least 10 times).

Procedure
Refer to the HemoPoint® H2 User’s Guide (or manual of the HemoCue® instrument) for proper use of the photometer.

Materials Provided
HemoPoint® H2 Microcuvettes, Cat.No. 3010-050

Materials Required But Not Provided
HemoPoint® H2 or HemoCue® Photometer
HemoPoint® H2 or HemoCue® Control Cuvette
HemoPoint® H2 Hemoglobin Controls, (Cat. No. 3600-601) Disposable pipettes (venous or arterial blood only)
Plastic film (venous or arterial blood only)
Lint-free material

Instructions For Use (Capillary)
1. Make sure that the Photometer is ready for use. See the HemoPoint® H2 User’s Guide or HemoCue® Operating Manual for the device.
2. Make sure that your patient is sitting comfortably.
3. There should be a good blood circulation in the hand from which you wish to take blood, e.g., it should be warm and relaxed.
4. Lightly massage the fingers, in order to stimulate circulation.
5. Disinfect the puncture site and allow to dry.
6. Take out a microcuvette from the container and close the lid immediately.
7. Press lightly on the fingertip with a suitable sampling device on the side of the fingertip.
8. Blot away the first drop of blood which usually is contaminated. If necessary, press gently once again to get a 2nd drop of blood which is large enough to fill the microcuvette completely. Avoid “milking” the finger.
9. Hold the tip of the microcuvette tip in the middle of the drop of blood and let the cavity fill in one step. In case of air bubbles in the optical eye, discard the microcuvette and take another sample using a new microcuvette.
10. In order to avoid contamination of the cuvette holder, measurement light must pass through the sample cuvette to the photo detector with the least possible interference. It is therefore crucial not to touch the optical eye of the cuvette with fingers, dirty or sharp objects.
Expected Values

The following hemoglobin values are considered normal:

- Adult males: 13.0 - 18.0 g/dL
- Adult females: 11.0 - 16.0 g/dL
- Children: 11.0 - 16.0 g/dL
- Infants (postnatal): 10.0 - 14.0 g/dL

Due to a wide range of conditions which affect normal values, it is recommended that each laboratory establish its own "normal" range.

References

3. HemoPoint® H2 Hemoglobin testing system User's Guide, Stanbio Laboratory, Boerne, Texas USA.

HemoCue® is a registered trademark of HemoCue AB, Angelholm, Sweden.

For Technical Service call: 800-531-5535 or (830) 249-0772
Fax: (830) 249-0881, e-mail: stanbio@stanbio.com
http://www.stanbio.com
Stanbio Laboratory 1251 North Main Street - Boerne, Texas 78006
DRI: RBA.301.02 + Last Revision: 07/04 + Procedure No. 3010
Categorization Notification Waived

Regulations codified at 42 CFR 493.15 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test systems or assay for the analyte is categorized below:

Test System: STANBIO HEMOGLOBIN ANALYZER
Analyte : HEMOGLOBIN
Complexity : Waived
510K or PMA Number : K032482

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for evaluation of waiver.

This complexity categorization is effective as of the date of this notification. This categorization will be reported on FDA's home page http://www.fda.gov/cdrh/clia. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. This categorization will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice. For questions regarding FDA's categorization procedure, contact Clara A. Sliva, Acting CLIA Coordinator, at (301)827-0496 or email at CLIA@CDRH.FDA.GOV

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
Exhibit 3.2

HemoPoint® H2 Cuvette Package Insert
Proprietary and established name:
HemoPoint® H2 Hemoglobin Cuvettes and HemoPoint® H2 Hemoglobin Photometer
Manufacturer: Stanbio Laboratory, Boerne, Texas 78006 USA

Intended Use
Quantitative determination of hemoglobin in arterial, venous, or capillary blood. For in vitro diagnostic use.
The HemoPoint® H2 system is intended to be used for the quantitative determination of hemoglobin (Hb) concentration in human blood. It consists of a photometer instrument and individual single-use microcuvettes filled with reagents.

Using the microcuvette, a small amount of arterial, venous or capillary blood is taken up by capillary action. The microcuvettes are intended to be used once only and must be disposed of after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment.

The HemoPoint® H2 system is designed for use in medical practices and in clinical laboratories to assist in medical diagnostic investigations. In addition it can be used in emergency and intensive care units and in medical facilities such as blood donor sessions and blood banks.

Blood sampling and operating the HemoPoint® H2 system should be carried out exclusively by clinically trained personnel with sound knowledge of the handling of in vitro diagnostic instruments and of this system.

HemoPoint® H2 cuvettes may also be used in combination with other compatible photometers.

Explanation and Summary of the Test
The recognized reference method for Hb determination (Hb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanmethemoglobin method. The blood sample is diluted 1:25 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron of the oxyhemoglobin and the desoxyhemoglobin becomes oxidized by potassium hexacyanoferrate (II). The bivalent iron of the oxyhemoglobin and the desoxyhemoglobin becomes oxidized by potassium hexacyanoferrate (II) to trivalent iron. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the Hb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN3 and thus he was able to reduce the toxicity of the reagent mixture considerably. Vanzetti’s method is also known as the azide methemoglobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

In the HemoPoint® H2, however, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood.
The filled cuvette is inserted into the HemoPoint® H2 photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb level is calculated and displayed.

Principle of Procedure
The Measurement Technique

In the HemoPoint® H2 photometer the light transmitted through the cuvette sample is measured.

\[ P_0 \text{ - 100% \ light intensity, } P \text{ - remaining light intensity, } b \text{ - distance through the solution} \]

For this purpose, light is directed through the blood sample and the transmission T is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using Lambert-Beer Law.

Light emitting diodes (LEDs) are used as light sources and a photodiode to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

The Microcuvette
The plastic microcuvette consists of a clear body with a cavity which takes an approx. 10 µl of blood which comes with dry reagents.
The optical distance between the cuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples.

The Chemistry Principle
In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary:

- sodium deoxycholate dissolves and disperses the cell walls of the red blood corpuscles. Hence the hemoglobin formerly contained in the erythrocytes is now available free in the solution.

- The bivalent iron of the oxyhemoglobin and the desoxyhemoglobin becomes oxidized by sodium nitrite NaNO2 to trivalent iron, in methemoglobin.

3 - 75°
Existing and formed methemoglobin and azide ions from sodium azide NaN₃ form a colored complex which exhibits maximal absorption at 540 and 575 nm and hence it can be quantitatively determined photometrically.

Illustration 1: Scheme of the reaction in determining hemoglobin using the azide methemoglobin method.

Reagents
Approximately 45% w/w sodium deoxycholate, Approximately 20% sodium azide, Approximately 20% Na₂ nitrite, Approximately 20% w/w non-reactive ingredients.

Warnings and Precautions
Microcuvettes are designed only for in-vitro diagnostics.
The reagents which coat the inner walls of the cuvettes are harmful and must not be swallowed.
Wear suitable protection (gloves) at all time when handling blood samples.
Please note that all human blood samples or products must be handled as potential infectious waste per your local regulations.

Storage
Store HemoPoint® H2 cuvettes at a temperature of 15°C - 30°C (59 - 86°F) at a dry place. Do not use a refrigerator for storage. Use cuvettes within 3 months after opening.

Handling the HemoPoint® H2 cuvettes
Store the microcuvettes solely in the original container at room temperature.
Only remove one microcuvette at a time from the container and then immediately close the lid again. Make sure that the lid is completely closed by pressing the lid firmly.
The microcuvettes are analyzed optically in the HemoPoint® H2 photometer. Measurement light must pass through the sample cuvette to the photo detector with the least possible interference. Therefore it is crucial not touch the optical eye of the cuvette with fingers or dirty or sharp objects.

Directions for use
Sample collection and preparation
The HemoPoint® H2 Photometer can be used with capillary, venous, or arterial blood. Venous and arterial blood samples may be used if the blood collected is not more than 24 hours old and the samples have been stored refrigerated (2-8°C). Prepare stored samples for measurement as follows:
- Remove sample tube from the refrigerator and bring it to room temperature.
- Mix the sample well. (e.g. by a mechanical rotator or hand inversion).

Procedure
Refer to the HemoPoint® H2 Operator's Manual (or manual of a compatible instrument) for proper use of the instrument.

Materials provided
HemoPoint® H2 Cuvettes

Materials required but not provided
HemoPoint® H2 photometer or other compatible photometer
HemoPoint® H2 Control cuvette
In case of using commercial blood controls, use controls recommended by Stanbio Laboratory only.
Lint-free material, e.g. gauze or Kleenex

Instructions for use
For capillary samples
- Take out a cuvette from the supply container and close it again tightly.
- Make sure that your patient is sitting comfortably. There should be a good blood circulation in the hand from which you wish to take blood, i.e. it should be warm and relaxed.
- Lightly massage the fingers, in order to stimulate the circulation.
For venous or arterial samples:

- Take out a cuvette from the supply container and close it again tightly.
- Remove sample tube from the refrigerator to bring it to the ambient temperature.
- Stir the sample well during tempering, e.g., by a mechanical rotator.
- Pipette a sufficient drop of blood on a non-absorbent material, e.g., plastic film.
- Avoid contamination of the cuvette holder, please remove surplus blood from the outside of the cuvette.

For infant samples:

- Children from 2 years to teenage, gradual increase to 13.0-18.0 g/dl.
- Infants (postnatal): 11.0-14.0 g/dl.
- Sulfhemoglobin cannot be measured by this method.

Expected values:

The following hemoglobin values are considered normal:

- Adult males: 13.0 - 18.0 g/dl.
- Adult females: 11.0 - 14.0 g/dl.
- Infants (postnatal): 11.0 - 14.0 g/dl.

Note: Children from 2 years to teenage, gradual increase to adult normals. Due to a wide range of conditions which effect normal values, it is recommended that each laboratory establish its own "normal" range.

Quality control:

Daily check of the system can be done by using the Control Cuvette, provided with the instrument. In case additional quality control checks are required for regulatory reasons, all commercially available controls can be used. Please check if these controls are recommended by Stanbio Laboratory. Do not use Sulfhemoglobin standards with this test.

Results:

The test result is displayed directly on the screen in the unit set before. The results are also stored in the built in memory or can be printed out. In case the result is above 26.5 g/dl, or equivalent, "value too high" is displayed.

Specific performance characteristics:

Precision:

Technical Data:

Within-run precision HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue Device ≤2%.

Experimental Data:

The precision evaluation experiment has been carried out in accordance with NCCLS 5 EP5-A. On each of 20 testing days two separate runs with duplicate measurements within each run were carried out. 3 commercially available control materials were used. The test was carried out using:

- 6 HemoPoint® H2-devices
- 2 HemoCue devices
- 16 lots of HemoPoint® H2 microcuvettes
- 3 operators.
HemoPoint® H2 Cuvette Proposed Package Insert

### Hemoglobin(high (17.3 g/dl))

<table>
<thead>
<tr>
<th>Hemoglobin(high (17.3 g/dl))</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EPS-A):</td>
<td>S= 0.111 g/dl, CV 0.6%</td>
<td>S= 0.103 g/dl, CV 0.9%</td>
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<tr>
<td>Total Precision (NCCLS EPS-A):</td>
<td>S= 0.202 g/dl, CV 1.2%</td>
<td>S= 0.162 g/dl, CV 0.9%</td>
</tr>
</tbody>
</table>

### Hemoglobin(low (10.7 g/dl))

<table>
<thead>
<tr>
<th>Hemoglobin(low (10.7 g/dl))</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EPS-A):</td>
<td>S= 0.096 g/dl, CV 0.9%</td>
<td>S= 0.068 g/dl, CV 0.9%</td>
</tr>
<tr>
<td>Total Precision (NCCLS EPS-A):</td>
<td>S= 0.114 g/dl, CV 1.1%</td>
<td>S= 0.095 g/dl, CV 0.9%</td>
</tr>
</tbody>
</table>

### Hemoglobin/normal (12.9 g/dl)

<table>
<thead>
<tr>
<th>Hemoglobin/normal (12.9 g/dl)</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EPS-A):</td>
<td>S= 0.084 g/dl, CV 0.7%</td>
<td>S= 0.102 g/dl, CV 0.8%</td>
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<td>Total Precision (NCCLS EPS-A):</td>
<td>S= 0.148 g/dl, CV 1.1%</td>
<td>S= 0.134 g/dl, CV 1.0%</td>
</tr>
</tbody>
</table>

### Between-Day Imprecision

| Single observation, 20 days | 10.7 g/dl, SD 0.160 g/dl, CV 1.0% | 10.9 g/dl, SD 0.164 g/dl, CV 0.9% |
|-------------------------------|------------------------------------------|
| 12.9 g/dl, SD 0.141 g/dl, CV 1.1% | 13.9 g/dl, SD 0.125 g/dl, CV 1.0% |
| 17.3 g/dl, SD 0.159 g/dl, CV 1.0% | 17.2 g/dl, SD 0.148 g/dl, CV 0.9% |

### Correlation Study:

#### Technical Data:

- Correlation coefficient HemoPoint® H2 System compared to NCCLS H15-A3 reference method, venous blood: ≥0.98
- Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to HemoCue System, venous blood: ≥0.97

#### Experimental Data:

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

<table>
<thead>
<tr>
<th>Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dl), venous blood</th>
<th>( Y = 0.323 + 1.006X )</th>
</tr>
</thead>
<tbody>
<tr>
<td>R=0.999</td>
<td>N=174, duplicate measurements</td>
</tr>
<tr>
<td>Range 3.31 g/dl to 24.4 g/dl</td>
<td>(Summary from measurements at 4 Clinical study Sites)</td>
</tr>
</tbody>
</table>

HemoPoint® H2 cuvettes measured in HemoCue device:

<table>
<thead>
<tr>
<th>Regression line and correlation coefficients compared to HemoCue system (g/dl), venous blood,</th>
<th>( Y = -0.233 +1.001X )</th>
</tr>
</thead>
<tbody>
<tr>
<td>R=0.998</td>
<td>N=286, duplicate measurements</td>
</tr>
<tr>
<td>Range 3.25 g/dl to 23.85 g/dl</td>
<td>(Summary from 4 Clinical Study Sites)</td>
</tr>
</tbody>
</table>

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoCue device):

<table>
<thead>
<tr>
<th>Regression line and correlation coefficients compared to HemoCue system (g/dl), venous blood,</th>
<th>( Y = 0.129 - 986X )</th>
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<tbody>
<tr>
<td>R=0.999</td>
<td>N=285, duplicate measurements</td>
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<tr>
<td>Range 3.25 g/dl to 23.85 g/dl</td>
<td>(Summary from 4 Clinical Study Sites)</td>
</tr>
</tbody>
</table>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Bibliography

3. HemoPoint® H2 Hemoglobin measuring system Operator's Manual, Stanbio Laboratory, Boerne, Texas USA.

HemoCue® is a registered trademark of HemoCue AG, Angelholm Sweden.
Exhibit 3.3

HemoPoint® H2 Cuvette Tube Label
HemoPoint™ H2
50 Hemoglobin Cuvettes

For Use with HemoPoint™ H2 Meter and HemoCue® Meter

Contents: 50 Single-Use Hgb cuvettes

For in Vitro Diagnostic Use

Store at 15 - 30° C

CAT. NO. 3011-050
LOT NO. 0311102 EXP: MAY 04

Date Opened

Use within 90 days of date opened.

STANBIO LABORATORY • 1261 North Main • Boerne, TX USA 78006
August 5, 2003

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food & Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510 (k) Notification – HemoPoint® H2 Hemoglobin Measurement System and HemoPoint® H2 Cuvettes

Attention: Document Control Clerk

This is to notify the Agency of the intention of Stanbio Laboratory to manufacture and market the following device:

HemoPoint® H2 Hemoglobin Measurement System.

Stanbio Laboratory requests the Food & Drug Administration hold as confidential information our intent to market the HemoPoint® H2 Hemoglobin Measurement System and therefore exempt from public disclosure.

An Indications for Use Statement follows this Cover Letter

A table of contents follows. Major sections are organized with index tabs per DRCND 510(k) Guidance Documents.

Please address all questions and comments regarding this submission to Mr. Kirk Johnson at Stanbio Laboratory.

Sincerely yours,

Kirk Johnson
QA/Regulatory Affairs Manager
Enc.
RECEPTION OK

<table>
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</tbody>
</table>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
June 3, 2004

Document Mail Center
HFZ-401
FDA/CDRH
9200 Corporate Blvd.
Rockville, MD 20850
OCT 24 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
Page 2

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known): K 032482

Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications for use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR. Over the Counter Use

(Optional Format 1-2-96) 19

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
**HemoPoint® H2 Microcuvettes**

**Procedure No. 3010**

For the quantitative determination of hemoglobin in capillary, venous or arterial whole blood.

**CLIA Complexity: Waived**

### Intended Use

The HemoPoint® H2 microcuvettes are intended to be used in the HemoPoint® H2 Photometer and the HemoCue® 8-Hemoglobin Photometer. The reagents/microcuvettes and the photometer form an analytical system.

### Summary and Principle

The HemoPoint® H2 system is intended to be used for the quantitative determination of hemoglobin (Hgb) concentration in human blood. It consists of a photometer instrument and individual single-use microcuvettes filled with reagents. Using the microcuvette, a small amount of capillary, venous or arterial blood is taken up by capillary action. The microcuvettes are intended to be used once only and must be disposed of after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment. The HemoPoint® H2 system is designed for use in medical practices and in clinical laboratories to assist in medical diagnostics. In addition, it can be used in emergency and intensive care units and in medical facilities such as blood donor sessions and blood banks. Blood sampling and operating the HemoPoint® H2 system should be carried out by trained personnel with sound knowledge of the system. HemoPoint® H2 cuvettes can also be used in combination with the HemoCue® photometer.

The recognized reference method for total hemoglobin is the cyanmethemoglobin method, which is also known as the cyanmethemoglobin method. The blood sample is diluted 1:25 with a reagent buffer solution. Here the erythrocytes are hemolyzed and the bivalent iron in oxyhemoglobin and deoxyhemoglobin are oxidized by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the Hgb concentration. In 1956, Vanzetti suggested to replace KCN by NaN₃ and thus he was able to reduce the toxicity of the reagent mixture considerably. Vanzetti’s method is also known as the azide methemoglobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

### Principles of the Procedure

In the HemoPoint® H2 system, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled microcuvette is inserted into the HemoPoint® H2 photometer, the color produced by the chemical reaction in the cuvette is measured, and the hemoglobin level is calculated and displayed. For this purpose, light is directed through the blood sample and the absorption is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using the Beer-Lambert law. Light emitting diodes (LEDs) are used as light sources, and a photodiode is used to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

### The Microcuvette

The plastic microcuvette consists of a cavity with a wall that takes up approximately 10 μl of blood which combines with the dry reagent chemistry. The optical distance between the cuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples.

### The Chemistry Principle

In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary: sodium deoxycholate dissolves and disperses the cell walls of the red blood corpuscles. Hence the hemoglobin formerly contained in the erythrocytes is now available free in the solution. The bivalent iron of the oxyhemoglobin and the deoxyhemoglobin becomes oxidized by sodium nitrite NaNO₂ to trivalent iron in methemoglobin. Existing and formed methemoglobin and azide ions from sodium azide NaN₃ form a colored complex which exhibits maximal absorption at 560 and 575 nm and hence it can be quantitatively determined photometrically.

### Reagents

**HemoPoint® H2 Microcuvettes, Cat. No. 3011**

40% w/w sodium deoxycholate, 25% sodium azide, 25% w/w sodium nitrite and 10% w/w non-reactive ingredients.

### Warnings and Precautions

Microcuvettes are designed for in-vitro diagnostic use only. The reagents which coat the inner walls of the microcuvettes are harmful and must not be swallowed. Wear suitable protection (gloves) at all times when handling blood samples. Please note that all human blood samples or products must be handled as potential infectious waste per your local regulations.

### Storage

HemoPoint® H2 microcuvettes are to be stored solely in the original container and at room temperature 59 – 86°F (15 – 30°C). DO NOT refrigerate! Use cuvettes within 3 months after opening container. Document the initial opening date or the container label in the space provided. Only remove one microcuvette at a time from the container and then immediately close the lid. The microcuvettes are analyzed optically in the HemoPoint® H2 photometer.

Measurement light must pass through the sample cuvette to the photo detector with the least possible interference. It is therefore crucial not to touch the optical eye of the cuvette with fingers, dirty or sharp objects.

### Sample Collection and Preparation

The HemoPoint® H2 Photometer can be used with capillary, venous, or arterial blood. Use EDTA, heparin or heparin/fluoride as anticoagulants, preferably in solid form, to avoid dilutional effects. Venous and arterial blood samples may be used if the blood collected is not more than 24 hours old and the samples have been stored refrigerated 35 – 46°F (2-8°C).

Prepare stored samples for measurement as follows:

1) Remove sample tube from the refrigerator and bring to room temperature.
2) Mix the sample tube well. (i.e. by a mechanical rotor or hand inversion at least 10 times).

### Procedure

Refer to the HemoPoint® H2 User’s Guide (or manual of the HemoCue® instrument) for proper use of the photometer.

### Materials Provided

**HemoPoint® H2 Microcuvettes, Cat. No. 3010-500**

### Materials Required But Not Provided

**HemoPoint® H2 or HemoCue® Photometer**

**HemoPoint® H2 or HemoCue® Control Cuvette**

**HemoPoint® H2 Hemoglobin Controls, (Cat. No. 3060-601)**

Disposable pipettes (venous or arterial blood only)

Plastic film (venous or arterial blood only)

Lint-free material.

### Instructions For Use (Capillary)

1. Make sure that the Photometer is ready for use. See the HemoPoint® H2 User’s Guide or HemoCue® Operating Manual for the device.
2. Make sure that your patient is sitting comfortably.
3. There should be a good blood circulation in the hand from which you wish to take blood, e.g., it should be warm and relaxed.
4. Lightly massage the fingers, in order to stimulate circulation.
5. Disinfect the puncture site and allow to dry.
6. Take out a microcuvette from the container and close the lid immediately.
7. Press lightly on the fingertip and puncture with a suitable sampling device on the side of the fingertip.
8. Blot away the first drop of blood then, if necessary, press gently once again to get a 2nd drop of blood which is large enough to fill the microcuvette completely. Avoid "milking" the finger.
9. Hold the tip of the microcuvette tip in the middle of the drop of blood and let the cavity fill in one step. In case of air bubbles in the optical eye, discard the microcuvette and take another sample using a new microcuvette.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Expected Values

The following hemoglobin values are considered normal:

- Adult males: 13.0 - 18.0 g/dL
- Adult females: 11.0 - 16.0 g/dL
- Children: 11.0 - 16.0 g/dL
- Infants (postnatal): 10.0 - 14.0 g/dL

Due to a wide range of conditions which affect normal values, it is recommended that each laboratory establish its own "normal" range.

Quality Control

The control cuvette must be read each day of testing using the appropriate control cuvette provided with the photometer. Good Laboratory Practices recommend the daily use of external controls to assure that the microcuvettes and the photometer are performing correctly. For this purpose, we recommend the use of Stanbio's HemoPoint® H2 Hemoglobin Controls Cat.No. 1460-601. Do not use Cyanmethemoglobin standards with this test.

Results

The test result is displayed directly on the screen of the HemoPoint® H2 or the HemoCue® photometer. No calculations are necessary. The test is linear up to 22.5 g/dL.

Performance Characteristics

Precision

Within-run precision using the HemoPoint® H2 and the HemoCue® devices with the HemoPoint® H2 microcuvettes is 2%. The precision evaluation was carried out in accordance with NCCLS EP8-A1. On each of 20 testing days, two separate runs with duplicate measurements were carried out. Three commercially available control materials were used. The test was carried out using: (9) HemoPoint® H2 devices; (2) HemoCue® devices; (6) lots of HemoPoint® H2 microcuvettes and (3) operators.

Correlation

Correlation coefficient of the HemoPoint® H2 System compared to the NCCLS H15-A3 reference method. Venous blood: r = 0.98

Correlation coefficient of the HemoPoint® H2 microcuvettes on the HemoCue® device compared to HemoCue® System. Venous blood: r = 0.97

Expected Values

- Adult males: 13.0 - 18.0 g/dL
- Adult females: 11.0 - 16.0 g/dL
- Children: 11.0 - 16.0 g/dL
- Infants (postnatal): 10.0 - 14.0 g/dL

Quality Control

The control cuvette must be read each day of testing using the appropriate control cuvette provided with the photometer. Good Laboratory Practices recommend the daily use of external controls to assure that the microcuvettes and the photometer are performing correctly. For this purpose, we recommend the use of Stanbio's HemoPoint® H2 Hemoglobin Controls Cat.No. 1460-601. Do not use Cyanmethemoglobin standards with this test.

Results

The test result is displayed directly on the screen of the HemoPoint® H2 or the HemoCue® photometer. No calculations are necessary. The test is linear up to 22.5 g/dL.

Performance Characteristics

Precision

Within-run precision using the HemoPoint® H2 and the HemoCue® devices with the HemoPoint® H2 microcuvettes is 2%. The precision evaluation was carried out in accordance with NCCLS EP8-A1. On each of 20 testing days, two separate runs with duplicate measurements were carried out. Three commercially available control materials were used. The test was carried out using: (9) HemoPoint® H2 devices; (2) HemoCue® devices; (6) lots of HemoPoint® H2 microcuvettes and (3) operators.

Correlation

Correlation coefficient of the HemoPoint® H2 System compared to the NCCLS H15-A3 reference method. Venous blood: r = 0.98

Correlation coefficient of the HemoPoint® H2 microcuvettes on the HemoCue® device compared to HemoCue® System. Venous blood: r = 0.97

References

3. HemPoint® H2 Hemoglobin testing system User's Guide, Stanbio Laboratory, Boerne, Texas USA.
6. Stanbio Laboratory, Boerne, Texas USA. HemoCue® System: (HemoPoint®) 1999.
9. HemPoint® H2 Hemoglobin testing system User's Guide, Stanbio Laboratory, Boerne, Texas USA.
13. HemPoint® is a registered trademark of HemoCue AB, Ängelsholm, Sweden.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIAAGENCY@fda.hhs.gov or 301-796-8118
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Your next step

- Online letter (no signature)
- Fax Letter (no signature)
- Make a new request

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***********************
*** RX REPORT ***
***********************

RECEPTION OK

| TX/RX NO | 6975 |
| CONNECTION TEL | 830 249 0892 |
| SUBADDRESS | STANBIO LABORATO |
| CONNECTION ID | 06/08 18:04 |
| ST. TIME | 02'19 |
| USAGE T | 8 |
| PGS. | |
| RESULT | OK |
Mr. Kirk Johnson  
Stanbio Laboratory  
1261 North Main St.  
Boerne, TX 78006  
US

Re: k032482  
Received: August 12, 2003

Waiver Granted Notification

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed it's review of your application for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. We are pleased to inform you that your test system(s) as identified below is waived:

Test System/Analyte(s): (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved or cleared by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver.

This complexity categorization is effective as of the date of this notification. This categorization will be reported on FDA's home page [http://www.fda.gov/cdrh/clia](http://www.fda.gov/cdrh/clia). This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. This categorization will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you have any questions regarding this complexity categorization, please contact Josephine Bautista at 240-276-0493 X107.

Sincerely yours,

Steven Gutman, M.D., M.B.A.  
Director  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health
Document Number: k032482

Test System: Stanbio HemoPoint H2 Hemoglobin Measurement System
Analyte: Hemoglobin
Complexity: WAIVED
Document Number: k032482

Test System: Stanbio HemoPoint H2 Hemoglobin Measurement System
Analyte: Hemoglobin
Complexity: WAIVED [0]
Rationale: WVD-003

ATTACHMENT

Records processed under FOIA Request 2014-5238; Released 10/16/14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Mr. Kirk Johnson  
QA/Regulatory Affairs Manager  
Stanbio Laboratory  
1261 North Main Street  
Boerne, Texas  78006

Re:  k032482  
Trade/Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System  
Regulation Number: 21 CFR § 864.5620  
Regulation Name: Automated Hemoglobin System  
Regulatory Class: II  
Product Code: GKR  
Dated: August 5, 2003  
Received: August 12, 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications for use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.
August 12, 2003

STANBIO LABORATORY
1261 NORTH MAIN ST.
BOERNE, TX 78006
ATTN: KIRK JOHNSON

510(k) Number: K032482
Received: 12-AUG-2003
Product: STANBIO LABORATORY
HEMOPOIN H2
HEMOGLOBIN MEASUREMENT SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/cdrh/ode/mdufma).

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health
See Instructions Before Completing This Cover Sheet

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates can be found at the following website: http://www.accessdata.fda.gov/scripts/cber/MDUFMA/index.cfm. The following three actions must be taken to properly submit your premarket application and fee payment:

1. FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent.
2. Include a copy of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the premarket application.) Also remember that the Payment Identification Number must be written on the check.
   If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to: US Bank, 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
3. Include a copy of this completed cover sheet in volume one of the premarket application when submitting to the Food and Drug Administration at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city, state, country, and post office code)
   STANBIO LABORATORY
   1281 NORTH MAIN STREET
   BOERNE, TX 78006
   US
   1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
   741339774

2. CONTACT NAME
   KIRK JOHNSON

2.1 E-MAIL ADDRESS
   kjohnson@stanbio.com

2.2 TELEPHONE NUMBER (Include area code)
   830-249-0772

2.3 FACSIMILE (FAX) NUMBER (Include area code)
   830-249-0851

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following website: http://www.fda.gov/oc/medufma)

Select an application type:
- [ ] Premarket notification (510(k)); except for third party reviews
- [ ] Biologic License Application (BLA)
- [ ] Premarket Approval Application (PMA)
- [ ] Modular PMA
- [ ] Product Development Protocol (PDP)
- [ ] Premarket Report (PMR)

3.1 Select one of the types below:
- [ ] Original Application

Supplement Types:
- [ ] Efficacy (BLA)
- [ ] Panel Track (PMA, PMR, PDP)
- [ ] Real-Time (PMA, PMR, PDP)
- [ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[ ] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologic application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA))

[ ] YES
[ ] NO
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)
August 5, 2003

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food & Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: 510 (k) Notification – HemoPoint® H2 Hemoglobin Measurement System and HemoPoint® H2 Cuvettes

Attention: Document Control Clerk

This is to notify the Agency of the intention of Stanbio Laboratory to manufacture and market the following device:

HemoPoint® H2 Hemoglobin Measurement System.

Stanbio Laboratory requests the Food & Drug Administration hold as confidential information our intent to market the HemoPoint® H2 Hemoglobin Measurement System and therefore exempt from public disclosure.

An Indications for Use Statement follows this Cover Letter.

A table of contents follows. Major sections are organized with index tabs per DRCND 510(k) Guidance Documents.

Please address all questions and comments regarding this submission to Mr. Kirk Johnson at Stanbio Laboratory.

Sincerely yours,

Kirk Johnson
QA/Regulatory Affairs Manager

Enc.
510(k) Number (if known): K032482

Device Name: Stanbio Laboratory HemoPoint® H2 Hemoglobin Measurement System

Indications for use:

The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and compatible measurement systems. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over the Counter Use
(Per 21 CFR801.109)
## 510(k) Submission Contents Outline:
**Stanbio HemoPoint® H2 Hemoglobin Measurement System**

<table>
<thead>
<tr>
<th>Subject</th>
<th>Page</th>
<th>Exhibit</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Submission Cover Letter</td>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td>Indications Page</td>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td><strong>Section 1-General Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Information</td>
<td>1-1</td>
<td></td>
</tr>
<tr>
<td><strong>Section 2- Statements/Certifications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>510(k) Summary of Safety and Effectiveness</td>
<td>2-2</td>
<td></td>
</tr>
<tr>
<td>Statement of Truth and Accuracy</td>
<td>2-5</td>
<td></td>
</tr>
<tr>
<td><strong>Section 3- Device Labeling</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Labeling Overview</td>
<td>3-1</td>
<td></td>
</tr>
<tr>
<td>HemoPoint® H2 Operator's Manual</td>
<td>3-2</td>
<td>Ex. 3.1</td>
</tr>
<tr>
<td>HemoPoint® H2 Cuvette Package Insert</td>
<td>3-74</td>
<td>Ex. 3.2</td>
</tr>
<tr>
<td>Microcuvette Vial Label</td>
<td>3-80</td>
<td>Ex. 3.3</td>
</tr>
<tr>
<td><strong>Section 4- Device Description</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Description- Narrative</td>
<td>4-1</td>
<td></td>
</tr>
<tr>
<td>System Specification</td>
<td>4-18</td>
<td>Ex. 4.1</td>
</tr>
<tr>
<td>Overall Dimensions- HemoPoint® H2</td>
<td>4-22</td>
<td>Ex. 4.2</td>
</tr>
<tr>
<td>Schematic Diagrams</td>
<td>4-27</td>
<td>Ex. 4.3</td>
</tr>
<tr>
<td>Specifications – 6V DC Mains Power Supply</td>
<td>4-32</td>
<td>Ex. 4.4</td>
</tr>
<tr>
<td>Seiko DPU-414 Printer Data Sheet</td>
<td>4-36</td>
<td>Ex. 4.5</td>
</tr>
<tr>
<td><strong>Section 5- Comparative Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comparative Information- Narrative Summary</td>
<td>5-1</td>
<td></td>
</tr>
<tr>
<td>Claims Matrix - comparing HemoPoint® H2 and predicate device claims</td>
<td>5-6</td>
<td>Ex. 5.1</td>
</tr>
<tr>
<td>Specification Matrix - comparing HemoPoint® H2 and predicate device specifications</td>
<td>5-8</td>
<td>Ex. 5.2</td>
</tr>
<tr>
<td>HemoCue Blood Hemoglobin Photometer Operating Manual</td>
<td>5-12</td>
<td>Ex. 5.3</td>
</tr>
<tr>
<td>HemoCue B-Hemoglobin Data Management Analyzer Manual</td>
<td>5-31</td>
<td>Ex. 5.4</td>
</tr>
<tr>
<td>HemoCue B-Hemoglobin Microcuvettes Package Insert</td>
<td>5-96</td>
<td>Ex. 5.5</td>
</tr>
<tr>
<td>SpunCrit Micro Hematocrit/Hemoglobin Analyzer Operation Manual</td>
<td>5-98</td>
<td>Ex. 5.6</td>
</tr>
<tr>
<td>Summary of Safety and Effectiveness for SpunCrit Micro Hematocrit/Hemoglobin Analyzer (K961803)</td>
<td>5-128</td>
<td>Ex. 5.7</td>
</tr>
<tr>
<td>Careside Hemoglobin Cartridge Package Insert</td>
<td>5-138</td>
<td>Ex. 5.8</td>
</tr>
<tr>
<td>Summary of Safety and Effectiveness for Careside Hemoglobin Cartridge (K001462)</td>
<td>5-146</td>
<td>Ex. 5.9</td>
</tr>
</tbody>
</table>
**510(k) Submission Contents Outline:**

**Stanbio HemoPoint® H2 Hemoglobin Measurement System**

<table>
<thead>
<tr>
<th>Subject</th>
<th>Page</th>
<th>Exhibit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Section 6- Clinical Equivalency Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Information- Narrative Summary</td>
<td>6-1</td>
<td></td>
</tr>
<tr>
<td>Clinical Study Protocol – Validation of the in-vitro diagnostic system</td>
<td>6-13</td>
<td>Ex. 6.1</td>
</tr>
<tr>
<td>“Hemo_Control / HemoPoint® H2,” data collection forms associated with the study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethics Committee Information and Approval Letter(s)</td>
<td>6-36</td>
<td>Ex. 6.2</td>
</tr>
<tr>
<td>Subject Informed Consent forms</td>
<td>6-48</td>
<td>Ex. 6.3</td>
</tr>
<tr>
<td>Clinical Study Report</td>
<td>6-63</td>
<td>Ex. 6.4</td>
</tr>
<tr>
<td>Internal Precision Study Report</td>
<td>6-116</td>
<td>Ex. 6.5</td>
</tr>
<tr>
<td>Stability Study Results</td>
<td>6-120</td>
<td>Ex. 6.6</td>
</tr>
<tr>
<td>Published literature supporting estimation of Hematocrit</td>
<td>6-122</td>
<td>Ex. 6.7</td>
</tr>
<tr>
<td>Published literature of Hemoglobin measurement technique</td>
<td>6-130</td>
<td>Ex. 6.8</td>
</tr>
<tr>
<td><strong>Section 7- Sterilization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaning and Disinfection Overview</td>
<td>7-1</td>
<td></td>
</tr>
<tr>
<td>HemoPoint® H2 Cleaning Instructions (from User’s Manual)</td>
<td>7-2</td>
<td></td>
</tr>
<tr>
<td><strong>Section 8- Software Validation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Software Validation Narrative Summary</td>
<td>8-1</td>
<td></td>
</tr>
<tr>
<td>Level of Concern</td>
<td>8-1</td>
<td></td>
</tr>
<tr>
<td>Software Descriptive Overview</td>
<td>8-2</td>
<td></td>
</tr>
<tr>
<td>Software Development Lifecycle Activities</td>
<td>8-3</td>
<td></td>
</tr>
<tr>
<td>Software Risk Management Activities - Discussion</td>
<td>8-7</td>
<td></td>
</tr>
<tr>
<td>Software Verification and Validation Results - Discussion</td>
<td>8-10</td>
<td></td>
</tr>
<tr>
<td>HemoPoint® H2 Functional Requirements Specification</td>
<td>8-11</td>
<td>Ex. 8.1</td>
</tr>
<tr>
<td>HemoPoint® H2 Software Requirements Specification</td>
<td>8-21</td>
<td>Ex. 8.2</td>
</tr>
<tr>
<td>HemoPoint® H2 Software Architecture Design Chart</td>
<td>8-32</td>
<td>Ex. 8.3</td>
</tr>
<tr>
<td>HemoPoint® H2 SHUMA- System Hazard Analysis/Risk Evaluation</td>
<td>8-34</td>
<td>Ex. 8.4</td>
</tr>
<tr>
<td>HemoPoint® H2 FMECA- Failure Mode Effects Report</td>
<td>8-55</td>
<td>Ex. 8.5</td>
</tr>
<tr>
<td>HemoPoint® H2 System Level Verification Report</td>
<td>8-86</td>
<td>Ex. 8.6</td>
</tr>
<tr>
<td>Product software quality assurance adherence certification of EKF</td>
<td>8-139</td>
<td>Ex. 8.7</td>
</tr>
<tr>
<td><strong>Section 9- Applicable Standards</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applicable Standards Narrative Summary</td>
<td>9-1</td>
<td></td>
</tr>
<tr>
<td>403.034 Safety requirements tests on the Hemo_Control equipment</td>
<td>9-3</td>
<td>Ex. 9.1</td>
</tr>
<tr>
<td>401.095 EMC tests on the Hemo_Control equipment</td>
<td>9-27</td>
<td>Ex. 9.2</td>
</tr>
<tr>
<td>EC Declaration of Conformity – Hemo_Control</td>
<td>9-62</td>
<td>Ex. 9.3</td>
</tr>
<tr>
<td>EC Declaration of Conformity – Seiko DPU 414 Printer</td>
<td>9-64</td>
<td>Ex. 9.4</td>
</tr>
</tbody>
</table>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Section 1: General Information

Trade Name: Stanbio Laboratory HemoPoint® H2 Hemoglobin Measurement System

Common/Classification Name: AUTOMATED HEMOGLOBIN SYSTEM

Establishment Registration Number:
Stanbio Laboratory registration number is 1616487.

Manufacturing Facility:
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006
Tel.: 830 249-0772
Fax: 830 249-0851
E-mail: kjohnson@stanbio.com

Device Classification: The devices are Class II medical devices in accordance with 21 CFR §864.5620. The devices have the Product Code GKR, and are reviewed by the Hematology panel.

Reason for Premarket Notification: This premarket notification is for a new device.

Substantial Equivalence to:

<table>
<thead>
<tr>
<th>K Number</th>
<th>Model</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>K961312</td>
<td>HemoCue B-Hemoglobin System with microcuvette</td>
<td>HemoCue</td>
</tr>
<tr>
<td>K832020</td>
<td>HemoCue Photometer</td>
<td>Leo Diagnostics/HemoCue</td>
</tr>
<tr>
<td>K961803</td>
<td>SpunCrit Model DRC 40</td>
<td>Micro Diagnostics Corp.</td>
</tr>
<tr>
<td>K001462</td>
<td>Careside Hemoglobin</td>
<td>Careside, Inc.</td>
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</table>

Applicable Performance Standards and Guidance Documents:
Conformance to applicable portions of the following performance standards has been exercised during product development:

<table>
<thead>
<tr>
<th>Standard</th>
<th>What Standard Addresses</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 60601-1 (03/96)</td>
<td>Medical Electrical Equipment - Part 1. General Requirements for Safety</td>
</tr>
<tr>
<td>AAMI/ISO 14971</td>
<td>Medical Devices: Application of Risk Management to Medical Devices</td>
</tr>
</tbody>
</table>

Conformance to applicable portions of the following standards and guidance documents has been evaluated during product development:

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>93/42/EEC</td>
<td>EU Law for Medical Products, device according to class IIa</td>
</tr>
<tr>
<td>HHS (FDA) 97-4224</td>
<td>In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions, January 1997</td>
</tr>
<tr>
<td></td>
<td>Guidance for FDA Staff- Regulating In Vitro Diagnostic Device (IVD) Studies, December 17, 1999</td>
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<tr>
<td></td>
<td>FDA Guidance Document- Reviewer Guidance for Premarket Notification Submissions, Portions applicable to Electromagnetic compatibility, Nov. 1993</td>
</tr>
<tr>
<td></td>
<td>Guidance for Industry: Acceptance of Foreign Clinical Studies, March 2001</td>
</tr>
<tr>
<td></td>
<td>Guidance for FDA Staff: Regulation of In Vitro Diagnostic Device Studies, December 17, 1999</td>
</tr>
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
### Section 1: General Information

<table>
<thead>
<tr>
<th>Title</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submissions for 510(k) Clearance, September 26, 1994</td>
<td></td>
</tr>
<tr>
<td>Guidance for Industry: Collection of Race and Ethnicity Data in</td>
<td></td>
</tr>
<tr>
<td>Clinical Trials, January 2003</td>
<td></td>
</tr>
<tr>
<td>Standards for Privacy of Individually Identifiable Health Information,</td>
<td>45 CFR parts 160 and 164 (per HIPAA regulations)</td>
</tr>
<tr>
<td>H03-A4 Procedures for the Collection of Diagnostic Blood Specimens</td>
<td></td>
</tr>
<tr>
<td>by Venipuncture Fourth Edition; Approved Standard, NCCLS</td>
<td></td>
</tr>
<tr>
<td>H04-A4 Procedures and Devices for the Collection of Diagnostic Blood</td>
<td></td>
</tr>
<tr>
<td>Specimens by Skin Puncture-Fourth Edition; Approved Standard,</td>
<td></td>
</tr>
<tr>
<td>NCCLS</td>
<td></td>
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<tr>
<td>H11-A3 Procedures for the Collection of Arterial Blood Specimens;</td>
<td></td>
</tr>
<tr>
<td>Approved Standard-Third Edition, NCCLS</td>
<td></td>
</tr>
<tr>
<td>EP9-A2 Method Comparison and Bias Estimation Using Patient Samples;</td>
<td></td>
</tr>
<tr>
<td>Approved Guideline-Second Edition; NCCLS</td>
<td></td>
</tr>
<tr>
<td>EP5-A Evaluation of Precision Performance of Clinical Chemistry</td>
<td></td>
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<tr>
<td>Devices; Approved Guideline, NCCLS, Vol. 19 No. 2, February 1999</td>
<td></td>
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</tbody>
</table>
Section Two – Statements/Certifications

Summary
Summary is included on page 2-2.

Statement of Truth and Accuracy
Statement of truth and accuracy is included on page 2-5
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

Trade Name: HemoPoint® H2 Hemoglobin Measurement System
Common/Classification Name: Automated Hemoglobin System
Device Classification:

- Class: II
- CFR: 21 CFR 864.5620
- Product Code: GKR

Manufacturer: Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

The recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here, the erythrocytes are hemolysed and the bivalent iron in oxy- and deoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN₃ and thus was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti’s method is also known as the azide methemoglobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

In the HemoPoint® H2, however, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled cuvette is inserted into the HemoPoint® H2 photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb level is calculated and displayed.

In the HemoPoint® H2 photometer the light transmitted through the cuvette sample is measured.

Principle of photometric transmitted light measurement.

\[ P_0: 100\% \quad \text{light intensity, } P: \text{remaining light intensity, } b: \text{distance through the solution} \]

For this purpose, light is directed through the blood sample and the transmission T is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using Lambert-Beers Law.

Light emitting diodes (LED’s) are used as light sources and a photodiode to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Intended Use:
The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative
determination of hemoglobin in arterial, venous, or capillary blood.
The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2
Hemoglobin Measurement System and compatible measurement systems. The microcuvettes
are intended to be used only once and must be disposed of after use as potentially infectious
waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin
ranges only (120 to 180 g/L or 12.0 to 18.0 g/dl). The estimated hematocrit is not indicative of
disease states such as anemia and abnormal values and will not be reported.

For In Vitro Diagnostic Use Only

Comparison To Predicate Device:

**Precision:**
Within-run imprecision HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue
Device ≤2%

<table>
<thead>
<tr>
<th>Hemoglobin/high (17.3 g/dL):</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision</td>
<td>( S_w = 0.111 \text{ g/dL}, \text{ CV } 0.6% )</td>
<td>( S_w = 0.103 \text{ g/dL}, \text{ CV } 0.6% )</td>
</tr>
<tr>
<td>Total Precision</td>
<td>( S_T = 0.207 \text{ g/dL}, \text{ CV } 1.2% )</td>
<td>( S_T = 0.162 \text{ g/dL}, \text{ CV } 0.9% )</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin/low (10.7 g/dL)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision</td>
<td>( S_w = 0.095 \text{ g/dL}, \text{ CV } 0.9% )</td>
<td>( S_w = 0.068 \text{ g/dL}, \text{ CV } 0.6% )</td>
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<tr>
<td>Total Precision</td>
<td>( S_T = 0.114 \text{ g/dL}, \text{ CV } 1.1% )</td>
<td>( S_T = 0.086 \text{ g/dL}, \text{ CV } 0.8% )</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin/normal (12.9 g/dL)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision</td>
<td>( S_w = 0.084 \text{ g/dL}, \text{ CV } 0.7% )</td>
<td>( S_w = 0.102 \text{ g/dL}, \text{ CV } 0.8% )</td>
</tr>
<tr>
<td>Total Precision</td>
<td>( S_T = 0.148 \text{ g/dL}, \text{ CV } 1.1% )</td>
<td>( S_T = 0.134 \text{ g/dL}, \text{ CV } 1.0% )</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Between-Day Imprecision</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Single observation, 20 days</td>
<td>( 10.7 \text{ g/dL}: SD 0.102 \text{ g/dL}, \text{ CV } 1.0% )</td>
<td>( 10.9 \text{ g/dL}: SD 0.094 \text{ g/dL}, \text{ CV } 0.9% )</td>
</tr>
<tr>
<td>12.9 g/dL: SD 0.141 \text{ g/dL}, \text{ CV } 1.1% )</td>
<td>( 13.0 \text{ g/dL}: SD 0.126 \text{ g/dL}, \text{ CV } 1.0% )</td>
<td></td>
</tr>
<tr>
<td>17.3 g/dL: SD 0.169 \text{ g/dL}, \text{ CV } 1.0% )</td>
<td>( 17.2 \text{ g/dL}: SD 0.148 \text{ g/dL}, \text{ CV } 0.9% )</td>
<td></td>
</tr>
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</table>

**Correlation Study:**

Correlation coefficient HemoPoint® H2 System compared to
NCCLS H15-A3 reference method, venous blood: \(\geq 0.98\)

Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to
HemoCue System, venous blood: \(\geq 0.97\)
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT’D

Experimental Data:

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

| Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood (Summary from 4 Clinical Study Sites) | - Y= 0.023 + 1.006X  
- R=0.999  
- N=174, duplicate measurements  
- Range 3.31 g/dL to 24.4 g/dL |
|---|---|
| Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites) | - Y= -0.233 +1.001X  
- R=0.998  
- N=286, duplicate measurements  
- Range 3.25 g/dL to 23.85 g/dL |

HemoPoint® H2 cuvettes measured in HemoCue device:

| Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites) | - Y= 0.139 +986X  
- R=0.999  
- N=286, duplicate measurements  
- Range 3.25 g/dL to 23.85 g/dL |

Comparison to Predicate Device:

<table>
<thead>
<tr>
<th>Specification</th>
<th>HemoPoint® H2</th>
<th>HemoCue</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Instrument :</td>
<td>No. 1</td>
<td>No. 2</td>
<td>No.1 ↔ No. 2</td>
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<tr>
<td>Measurement range</td>
<td>0 – 25.6 g/dL</td>
<td>0 – 25.6 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Specified range</td>
<td>0 – 25.6 g/dL</td>
<td>0 – 23.5 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Specified accuracy</td>
<td>± 0.3 g/dL at ≈14 g/dL</td>
<td>± 0.3 g/dL at ≈14 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Sample material</td>
<td>venous, arterial or capillary human blood</td>
<td>venous, arterial or capillary human blood</td>
<td>equivalent</td>
</tr>
<tr>
<td>Measuring time</td>
<td>Approximately 30 – 60 sec</td>
<td>Approximately 30 – 60 sec</td>
<td>measuring time depends on the concentration</td>
</tr>
<tr>
<td>Measuring units</td>
<td>mol/L, g/dL, g/L</td>
<td>mol/L, g/dL, g/L</td>
<td>equivalent</td>
</tr>
<tr>
<td>Calibration</td>
<td>against NCCLS reference method</td>
<td>against ICSH reference method</td>
<td>NCCLS is current version of the method</td>
</tr>
<tr>
<td>Method</td>
<td>Azidemethemoglobin method (Vanzetti)</td>
<td>Azidemethemoglobin method (Vanzetti)</td>
<td>equivalent</td>
</tr>
</tbody>
</table>

Conclusion / Substantial Equivalence:
The HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes and the predicate devices, HemoCue B-Hemoglobin System with microcuvette are substantially equivalent based on design and function.

Kirk Johnson  
QA/Regulatory Affairs Manager  
Stanbio Laboratory

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
I certify that, in my capacity as the QA/Regulatory Affairs Manager of Stanbio Laboratory, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Kirk Johnson - QA/Regulatory Affairs Manager

Stanbio Laboratory August 5, 2003
(Company Name) (Date)

(Premarket Notification [510(k)] number)
Section Three – Proposed Labeling

Proposed labeling and promotional materials are included in this section.

**HemoPoint® H2 Operator’s Manual**

The HemoPoint® H2 Operator’s Manual is included in Exhibit 3.1. This manual informs the patient on the proper use of the device, and includes sections on safety, proper set-up and operation, menu functions, accessories, and cleaning and maintenance. The manual uses a format of clearly identified warnings, cautions, and notes to inform the patient of important information.

**HemoPoint® H2 Package Insert**

Specific labeling is provided with the HemoPoint® H2 Cuvettes. This labeling is compiled to meet 21 CFR § 809.10, Labeling for in vitro diagnostic products. The cuvette Package Insert is included in Exhibit 3.2.

The Stanbio Laboratory Cuvettes can be used for both HemoPoint® H2 and HemoCue Hemoglobin measurement devices. Specific performance characteristics are described in the Package Insert for use of the Stanbio Laboratory Microcuvettes with both the HemoPoint® H2 and HemoCue measurement devices.

**HemoPoint® H2 Microcuvette Vial Label**

The Cuvette Vial Label is included in Exhibit 3.3. The vial label provides a description of the analyte measured, contents quantity, lot number information, life information, and a space for the user to write the date of container opening.
Exhibit 3.1

HemoPoint® H2 Operator’s Manual
HemoPoint® H2

Hemoglobin Photometer
User’s Guide
0. Table of contents

0. Table of contents ........................................................... 1
1. Important information ...................................................... 5
  1.1 Welcome! ................................................................... 5
  1.2 Explanation of the graphic symbols ............................. 5
  1.3 Safety notes ................................................................ 5
2. Intended use ........................................................................ 8
3. Set up .............................................................................. 9
  3.1 Unpacking the photometer .......................................... 9
  3.2 Setting up the photometer ......................................... 10
  3.3 Switching the photometer on and off ......................... 11
    3.3.1 Using for first time ................................................. 11
    3.3.2 To operate using the power adapter ..................... 12
    3.3.3 Battery operation ................................................... 14
    3.3.4 Stand-by mode ...................................................... 14
    3.3.5 Displays and symbols in the ready mode ............. 15
4. Sampling and testing procedure ........................................ 16
  4.1 Taking a sample ........................................................ 16
    4.1.1 Notes on using the microcuvettes ......................... 16
    4.1.2 Taking a sample of capillary blood ..................... 17
    4.1.3 Taking a sample of venous or arterial blood ......... 21
  4.2 Performing the test .................................................... 24
4.3 Quality control ........................................................... 28
    4.3.1 Blank reading ........................................................ 28
    4.3.2 Control cuvette ...................................................... 29
    4.3.3 External quality control .......................................... 31
5. Further functions ............................................................ 32
  5.1 Touchscreen ............................................................. 32
    5.1.1 General ................................................................. 32
    5.1.2 Meaning of the buttons / Navigation .................... 33
  5.2 Memory – (data storage) .............................................. 33
    5.2.1 Displaying results from memory ......................... 33
    5.2.2 Printing out results ................................................ 35
    5.2.3 Deleting the stored test data ................................. 35
  5.3 Menu functions .......................................................... 36
    5.3.1 Information about the photometer ....................... 37

HemoPoint® H2 User's Guide

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
# Table of contents

5.3.2 Setting the date ..................................................... 38  
5.3.3 Setting the time ..................................................... 39  
5.3.4 Setting the units .................................................... 39  
5.3.5 Hgb - limits ........................................................ 40  
5.3.6 Setting the display contrast ..................................... 40  
5.3.7 Settings ................................................................ 41  
   5.3.7.1 Setting the language ........................................ 41  
   5.3.7.2 Setting date format .......................................... 41  
   5.3.7.3 Setting time format ......................................... 42  
   5.3.7.4 Setting the power frequency ............................ 42  
5.3.8 Menu options ....................................................... 42  
   5.3.8.1 Output activation of hematocrit value .................. 42  
   5.3.8.2 Setting the print mode ..................................... 43  
5.4 Standard print mode .................................................. 43  
   5.4.1 Header ................................................................ 43  
   5.4.2 Range mode (On), Hematocrit (On) ...................... 44  
5.5 Expanded print mode ................................................ 44  
   5.5.1 Header ............................................................. 44  
   5.5.2 Range mode (On), Hematocrit (On) ...................... 44  
   5.5.2.1 Setting the tone signal .................................... 44  
   5.5.2.2 Setting the stand-by time ................................. 45  
   5.5.2.3 The history menu ............................................ 45  
   5.5.2.4 The service menu .......................................... 46  
5.5.3 Information on contacting us .................................... 46  
5.6 Connecting accessories ............................................. 46  
   5.6.1 Connecting a printer .......................................... 47  
   5.6.1.1 Connecting lead ............................................ 47  
6. Maintenance ................................................................ 49  
   6.1 Cleaning and disinfection of the instrument ............... 49  
   6.1.1 Housing and touchscreen .................................... 49  
   6.1.2 Cuvette holder .................................................. 49  
   6.1.3 Optical unit ...................................................... 50  
   6.1.4 Power adapter .................................................. 51  
6.2 Charging and care of the battery ................................. 51  
   6.2.1 Charging strategy .............................................. 51  
   6.2.2 Charging time .................................................... 52  
   6.2.3 Self discharge ................................................... 52  
6.3 Repairs .................................................................. 53  
6.4 Disposal management concept .................................... 53  
7. Troubleshooting .......................................................... 54
Table of contents

7.1 Problem solving................................................................. 54
7.2 Resetting of the photometer........................................... 61
8. Technical data........................................................................ 62
  8.1 HemoPoint® H2 photometer ........................................ 62
  8.2 Microcuvette.................................................................... 63
9. Reference range ..................................................................... 64
  9.1 Normal range .................................................................... 64
  9.2 Understanding your result................................................ 64
10. Appendix.................................................................................. 65
  10.1 List of replacement parts and consumer materials ... 65
  10.2 Further information....................................................... 66
11. Index....................................................................................... 67
Intentionally Blank
1. Important information

1.1 Welcome!
Congratulations on purchasing the HemoPoint® H2 hemoglobin testing system. Before you begin using your new HemoPoint® H2 system we strongly recommend you read this manual completely, with particular attention to the following section with its introductory explanations and safety notes.

1.2 Explanation of the graphic symbols

The DANGER symbol!
This symbol warns of situations or actions that could lead to serious damage to the health of the user or a patient.

The WARNING symbol!
This symbol warns about incorrect handling that could cause measuring errors or damage to the instrument or any accessories used.

The TIP symbol!
Alongside this symbol we provide useful additional information about the current matter.

1.3 Safety notes
It is essential that you read the following notes, in order to avoid risks to persons and damage to the photometer and other equipment. Stanbio Laboratory does not accept responsibility for damage arising from non-observance of the following notes.
Important information

Follow the user’s guide!
Each time the photometer is used, precise knowledge and attention to these operating instructions is required. Only use the HemoPoint® H2 system for the purpose which will be described in Section 2.

Danger of fatal electric shock!
- Under no circumstances should you open the AC power adaptor. There are no elements inside which require servicing or maintenance.
- Never use a mechanically damaged AC power adaptor – live connections might be exposed.
- The AC power adaptor is not waterproof. Therefore, never let liquids come into contact with it. A lightly dampened cloth, however, can be used to clean it when disconnected. Please see the notes on care in Section 6.
- Only use the AC power adaptor in a socket that has been properly installed.

Check that the AC voltage and frequency printed on the AC power adaptor label match your electrical socket and whether the shape and configuration of the plug contacts are compatible for this connection.

Not to be used in areas where there is a risk of explosion!
The instrument is not approved for use in areas where there is a risk of explosion.

Keep the photometer away from liquids!
The photometer is not waterproof. Fluids entering the instrument could destroy the electrical and optical components in the photometer. A lightly dampened cloth, however, can be used for cleaning. Please see the notes on care in Section 6.

Allow the instrument to reach room temperature!
Particularly on changing from a cold into a warm environment (e.g. after storage or transport) condensation can form inside and on the outside of the instrument. Wait an appropriate time.
(approx. 1 hour), before you connect to the main power supply or switch on the instrument.

**Only use original equipment!**
Only attach equipment that is expressly approved for use with the HemoPoint® H2. Stanbio does not guarantee the function of the instrument when other equipment is used.

**Never open the photometer!**
There are no parts in the photometer that require customer maintenance. Repairs can only be carried out by Stanbio Laboratory personnel. Further notes on maintenance can be found in Section 6.

**Do not force the cuvette holder!**
The cuvette holder is very important for the quality of testing. Therefore mechanical force on the holder should be avoided and only the designated microcuvettes should be used. For cleaning purposes the cuvette holder can be removed from the photometer after a mechanical locking device is released. Notes on this can be found in Section 6.
2. Intended use

The HemoPoint® H2 system is intended for the quantitative determination of hemoglobin (Hgb) in whole blood of adults, infants, and children in a professional point-of-care setting. It consists of a dedicated photometer and individual, single-use microcuvettes filled with reagents. Using the microcuvette, a small amount of arterial, venous or capillary blood is taken up by capillary action. The filled cuvette is inserted into the HemoPoint® H2 photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hgb value is displayed. The microcuvettes are intended to be used only once and must be disposed after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment.

The HemoPoint® H2 system is designed for use in medical practices and in clinical laboratories to assist in medical diagnostic investigations. In addition it can be used in emergency and intensive care units and in medical facilities such as blood banks. This test system has been approved for use in laboratories with Waived status as defined in 452 CFR 493.15(c)(a).

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3. **Set up**

3.1 **Unpacking the photometer**

Before you set up the HemoPoint® H2 photometer, first check that all the items are present and undamaged. (see illustration 1)


**Materials provided**
- One HemoPoint® H2 Photometer
- One (1) AC power adapter
- One (1) HemoPoint® H2 Control Cuvette
- One (1) User's Guide
- One (1) Quick Reference Guide
- One (1) Warranty Registration Card
Set up

**Additional materials required but not provided**
- Latex Gloves
- Sampling devices for capillary blood collection
- Biohazardous waste container
- Alcohol swabs and gauze for cleaning puncture site
- HemoPoint® H2 microcuvettes
- HemoPoint® H2 Hemoglobin Controls
- HemoPoint® H2 Optics Cleaner

**Why fill out the Warranty Registration Card?**
Returning the completed Warranty Registration Card will activate your warranty and allow Stanbio to provide you with the latest product updates and improvements.

**What is your voltage?**
*Check that the AC voltage and frequency printed on the AC adaptor label match your electrical socket and whether the shape of the plug is compatible for this connection. If not, do not connect the photometer to the electrical socket under any circumstances. Contact Stanbio Laboratory in this case.*

**3.2 Setting up the photometer**
Select a suitable place for setting up the photometer, according to the following criteria:
- avoid direct sunlight
- avoid strong electromagnetic fields
- avoid direct influence from ionizing radiation
- avoid rapid temperature fluctuations (keep away from heaters, open windows, ventilators, fans or air-conditioning, etc.)
- avoid wet areas (e.g. wash basins)

Place the photometer on a level counter adjacent to a power socket. Make sure there is enough room for the cuvette holder to be freely accessible.
3.3 Switching the photometer on and off

3.3.1 Using for first time

Allow the photometer to reach room temperature!

Changing from a cold to a warm environment, (e.g. after storage or transport) condensation can form both on the inside and the outside of the photometer. Wait at least 1 hour, before you connect the photometer to a power supply.

As the built-in battery has not yet been charged, the photometer must first be connected to the power adaptor (supplied) and plugged into an electrical socket until the battery is completely charged.

This procedure is necessary in order for the capacity of the battery to be checked and the charge indicator to function correctly. Further information on this can be found in Section 6.2 “Charging and care of the battery”
3.3.2 To operate using the power adapter

Use the power adapter to operate the photometer, noting the following steps when connecting the power adapter:

1. Insert the small round plug on the connecting cable of the power adapter into the appropriate socket (6VDC) at the back of the photometer.

Illustration 3: Connecting the power adaptor.

2. Next, insert the power adapter plug into an appropriate electrical socket. The photometer itself does not have a power On/Off switch.

Please be patient after plugging the photometer into the electrical socket. It may be 4 or 5 seconds before anything appears on the display. This does not indicate a fault but is related to various initialization steps within the photometer. Following this initialization phase, the display illuminates and a welcome screen appears briefly, after which the instrument is ready to operate.
Illustration 4: Welcome display screen.

Illustration 5: Display in ready mode.

The individual symbols and their meanings are explained in Section 3.3.5 "Displays and symbols in the ready mode".

Now you can either start your testing, view results in the memory, or carry out adjustments in the Menu.

You can find tips on this in Sections 4 "Sampling and Testing Procedure", 5.2 "Memory – data storage" and 5.3 "Menu functions".

If the photometer is not in use for some time, it switches into the energy-saving, Stand-By mode (see Section 3.3.4 "Stand By mode").
3.3.3 Battery operation

The HemoPoint® H2 photometer automatically switches to battery operation when you unplug the power adaptor from the electrical socket, or from the instrument (assuming, of course, that the battery is sufficiently charged).

When the battery is fully charged it will operate for a period of at least 100 hours. The display is not backlit when using battery power, in order to save energy.

Tips on charging the battery and battery maintenance can be found in Section 6.2 “Charging and care of the battery”.

To avoid problems while testing during battery operation, also note the tips in Section 3.2 “Setting up the photometer”.

3.3.4 Stand-by mode

The photometer does not have a separate On/Off-switch. It is designed so that it automatically switches to the Stand-By mode when you are not operating the instrument for a certain time (approximately 5 minutes). The display will go blank in the Stand-by mode.

This elapsed time can be changed in Menu Options - Stand-by (see Section 5.5.2.2 “Setting the Stand-by time”).

The Stand-By mode reduces current usage to a minimum. This ensures that the battery is never run down more than necessary.

There are (3) three ways of switching the instrument ON again:

• Touch the Touchscreen
• Open or close the cuvette holder
• Plug the photometer into an electrical power supply
3.3.5 Displays and symbols in the ready mode

Illustration 6: Display in ready mode.
4. Sampling and testing procedure

4.1 Taking a sample

4.1.1 Notes on using the microcuvettes

The microcuvette, as the most sensitive component in the HemoPoint® H2 system, is crucial for proper measuring quality. It is therefore necessary to handle the cuvette carefully, paying particular attention to the following conditions:

1. Each microcuvette can only be used once!

The microcuvette is designed for single use. The cuvette is coated during manufacturing with all the reagents necessary for determining the hemoglobin concentration in the blood sample. As soon as the blood is taken into the cuvette, a reaction occurs (within 3 minutes) and the reagents are consumed.

2. Microcuvettes are sensitive to moisture!

The microcuvettes will absorb moisture therefore the cuvettes are delivered in a special airtight container that contains a drying agent. This drying agent assures that any moisture is readily
Sampling and testing procedure

absorbed during storage and after a microcuvette is taken out of the container.

Pay attention to the following notes, to preserve the functionality of the cuvettes:

- Store the cuvettes only in the original container and at room temperature (59-86°F / 15-30°C).
- Only remove one cuvette at a time from the container and then immediately close the lid. Make sure that the lid is completely closed by pressing it down as far as it will go.

The cuvette expiration dating is considerably reduced once the seal of the container is broken and the lid is opened. See the HemoPoint® H2 cuvette container label for additional information. Please make a note of the date of opening on the container label.

3. Microcuvettes are precision optical components!

The microcuvettes are analyzed optically in the HemoPoint® H2 photometer. The measured absorption is proportional to the hemoglobin concentration. The light from the light source should penetrate through the sample to the photo detector with the least possible influence from the cuvette. Therefore it is important not to touch the optical eye of the cuvette with fingers or sharp objects.

4. Microcuvettes are only designed for in-vitro testing!

5. The reagents that coat the inner walls of the cuvette are harmful and must not be swallowed.

4.1.2 Taking a sample of capillary blood

1. Take out a microcuvette from the original container and close it again tightly.

WARNING! Please note Section 4.1.1 “Notes on using the microcuvettes”.

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Sampling and testing procedure

Illustration 8: Preparing to take a blood sample.

2. Make sure that your patient is sitting comfortably. There should be good blood circulation in the hand from which you wish to take blood, i.e. it should be warm and relaxed.

If in doubt, the hands can be warmed in warm water.

Illustration 9: Stimulating the circulation.

3. Lightly massage the fingers, in order to stimulate the circulation.
Warning, risk of infection!
Please wear suitable protective gloves!

Only use the middle or ring finger. To avoid blood stasis, the patient should not be wearing a ring on the finger used for sampling.

Illustration 10: Disinfecting the puncture site.

4. Disinfect the puncture site and allow to dry.

Illustration 11: Stick the finger.

5. Press lightly on the fingertip and puncture with a suitable sampling device from the side.
Sampling and testing procedure

**TIP**

Pricking the fingertip from the side is less painful and the blood flow at this site is better. To ensure to have a spontaneous flow of blood use a deep incision of approx. 2.25 mm.

Illustration 12: Blot away the first drop of blood.

6. Blot away the first drop of blood then, if necessary, press gently once again to get a blood of drop which is large enough to fill the cuvette completely, avoid "milking". (For additional information about obtaining a capillary blood sample, read the NCCLS guideline H4A4).

Illustration 13: Filling the cuvette.
7. Hold the tip of the cuvette in the middle of the drop of blood and let the cavity fill in one step.

Ensure that the cuvette cavity is filled and free of air bubbles, particularly in the optical eye area. Otherwise repeat the process with a new drop of blood and a new cuvette.

Illustration 14: Removing surplus blood.

8. In order to avoid contamination of the cuvette holder, remove surplus blood from the outside of the cuvette by carefully wiping off with a gauze or lint-free tissue.

Please note, do not remove any blood from the cuvette cavity.

The cuvette sample can now be tested immediately or within 10 minutes. Do not read cuvette after 10 minutes. For further steps, please read section 4.2 “Performing the test“.

4.1.3 Taking a sample of venous or arterial blood

The HemoPoint® H2 Photometer can be used for determination of hemoglobin in venous or arterial blood samples if the blood collection date is not longer than 24 hours and the sample was stored refrigerated (2-8°C). Prepare the sample for the measurement as follows:
Sampling and testing procedure

1. Remove sample tube from the refrigerator and bring it to room temperature (15-30°C).
2. Mix the sample well. (e.g. by a mechanical rotator or by inverting by hand)
3. Take out a microcuvette from the container and close the container again tightly.

*Please note Section 4.1.1 “Notes on using the microcuvettes”.

4. Pipette a sufficient drop of blood on a non-absorbent material, (e.g. plastic film).
5. Contact the tip of the cuvette with the drop of blood and wait until the cuvette is filled completely (see Illustration 15).

Illustration 15: Taking a sample of venous or arterial blood.

Ensure that the cuvette cavity is filled and free of air bubbles, particularly in the optical eye area. Otherwise repeat the process with a new drop of blood and a new cuvette.

6. In order to avoid contamination of the cuvette holder, remove surplus blood from the outside of the cuvette by carefully wiping off with a gauze or lint-free tissue. (see Illustration 14).
Please note, do not remove any blood from the cuvette cavity.

The cuvette sample can now be tested immediately or within 10 minutes. Do not read cuvette after 10 minutes. For the further steps, please read Section 4.2 “Performing the test”.

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4.2 Performing the test ("Hgb limit" mode ON with the Hct function ON)

Illustration 16: Opening the cuvette holder.

1. Open the cuvette holder completely.

Illustration 17: Display "Add Cuvette"

*The instrument will check the optical performance of the measuring system. This process takes approx. 1 - 2 seconds. Please release the cuvette holder and do not touch it again until the process is finished and an audible signal (beep) occurs.*
2. If you have the “Hgb limit” mode activated and set the normal range for each patient type (see section 5.3.5 “Hgb limits”), the display will show the patient types that can be selected before testing occurs. Select the patient type by touching the appropriate button. If you select “NO”, then no patient range will be used in the testing of the sample.

Illustration 18: Display “Select Patient Type”

In case you wish to change or cancel the selected patient type, simple touch the “Patient Type” button and make another selection.

Illustration 19: Inserting the cuvette.
Sampling and testing procedure

Illustration 20: Display after a patient type is chosen.

3. Insert the appropriate patient cuvette (example, Female) into the cuvette holder as shown in Illustration 19. (The cuvette is designed to fit only one way in the holder.)

4. Push gently on the cuvette holder and it will close automatically.

5. Testing of the cuvette begins automatically (see Illustration 21).

WARNING! Ensure the cuvette holder closes completely, otherwise the cuvette will not be positioned correctly in the photometer and this will cause incorrect results.

Illustration 21: Display during the testing cycle.

The HemoPoint® H2 photometer is now testing the hemoglobin concentration. The testing time varies according to the...
Sampling and testing procedure

Hemoglobin concentration and can take between 10 seconds and 3 minutes.

Symbols for violated Hgb-limits:
- M: Male
- C: Child
- +: Result above upper limit threshold
- -: Result below lower limit threshold

Illustration 22: Display showing the test result.

4. Read the test result.

You can now make a note of the result(s). Pressing the OK button is not absolutely necessary. It merely produces a confirmation of the result, while the photometer changes to the operational readiness display. Opening the cuvette holder will start a new testing cycle.

The hemoglobin result is displayed with the selected patient type and maybe marked with a (+) or (-) if the result falls outside the selected patient normal range. An estimated Hematocrit result will be displayed if the "Hct mode" is activated (see section 5.3.8.1 Hct mode). The measured result is stored and can be recalled later from the measured data store (Memory) which can hold up to 100 patient results (see Section 5.2.1 "Displaying results from memory").

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Sampling and testing procedure

If you have connected a printer, the current test result will be printed out immediately. Further information about connecting a printer can be found in Section 5.6.1 “Connecting a printer”.

If you prefer the display to show the result in another type of unit, you can change it, as described in Section 5.3.4 “Setting the units”.

5. Open the cuvette holder, take out the used cuvette and dispose properly.

When the holder is opened, a new testing cycle is started and the photometer checks the optical performance of the measuring system and automatically becomes ready for a new cuvette to be inserted.

If you do not want to perform another test, simply close the cuvette holder again. The test cycle will be interrupted.

4.3 Quality control

4.3.1 Blank reading

All the optical and mechanical components involved with the measuring cycle are carefully manufactured with extremely small tolerances. This is essential for the proper function of the photometer.

Always carry out a blank reading whenever you have removed the cuvette holder (i.e., cleaning, replacing with a new cuvette holder).

A blank reading can be performed as follows:

1. Open the cuvette holder completely and wait until the instrument is in testing mode.
The text in the display reads "testing mode".

2. Close the cuvette holder again, without inserting a cuvette.

In this case the photometer does not start testing. After approx. 2–3 seconds the display will again read "Add Cuvette". If the instrument does start testing, there is possibly a malfunction. Please consult Section 7 "Troubleshooting".

4.3.2 Control cuvette

The control cuvette supplied with the photometer can be used for a simple and economic check of the photometer's calibration. The measuring quality of the photometer should be checked once daily using this control cuvette.

Illustration 23: Control cuvette.

The Hgb value and the permitted deviation of the control cuvette are stated on the storage box. All photometers have a specific calibration because of the tolerances in the mechanical and electronic components. The control cuvettes are only calibrated for the instrument with which they are delivered, i.e. the Hgb value stated on the storage box is only valid for that one photometer,
and could lead to completely different results on other photometers.

**WARNING!**

*If you have several HemocPoint® H2 photometers, keep track of each control cuvette for each photometer.*

*Always keep the control cuvette in the original storage box. It is optimally protected there against breakage and contamination.*

To test the control cuvette, proceed as follows:

1. Open the cuvette holder completely and wait until the photometer is in testing mode.
2. Take the control cuvette out of the storage box and place it in the cuvette holder.
3. Close the cuvette holder completely.

*The photometer tests the control cuvette and shows the result after a few seconds.*

4. Compare the result with that stated on the storage box. The result must lie within the declared tolerances. Record the control result!

*If the Hgb result falls outside the range of the control cuvette, there is evidently a problem. Please consult Section 7 “Troubleshooting” in this regard.*

If the original control cuvette is lost or damaged, the photometer must be checked for proper calibration and a new control cuvette must be assayed. The photometer will need to be sent back to Stanbio Laboratory for a new control cuvette assignment at considerable expense to you.
4.3.3 External quality control

Good Laboratory Practices recommends the use of external controls to assure that the microcuvettes and the photometer are performing correctly. For this purpose, we recommend the use of Stanbio HemoPoint® H2 Hemoglobin Controls.

Two (2) different control preparations are provided in the set.

With the help of these two (2) different concentrations you can easily assess the precision of the system.

Instructions for ordering can be found in Section 10.1 “Lists of replacement parts and consumer materials”.

There are a variety of hemoglobin controls on the market today. Stanbio only recommends the use of the HemoPoint® H2 Hemoglobin Controls, since we cannot guarantee the compatibility of other brands of controls on the HemoPoint® H2 system.

Thoroughly mix the controls before use. (see the control package insert for directions for use).

**Compare the values obtained with the controls against the stated reference values. If there are deviations refer to Section 7 “Troubleshooting”**.
5. Further functions

5.1 Touchscreen

5.1.1 General

The photometer has been equipped with a touchscreen. The touch sensitive surface is divided into various individual segments. According to the current operating mode, these segments can be defined as operating buttons.

Illustration 24: Divided touchscreen.

The buttons in the lower part of the display are enlarged to allow easy operation. As can be seen in Illustration 24, the sensitive area of these buttons extends into the middle of the display, so it is not difficult to operate them.

Operating the touchscreen is only possible in the operational mode (cuvette holder closed and no testing in progress).

A touchscreen is a delicate electronic component. Therefore please note the following instructions:

- Only touch the touchscreen lightly with fingertips.
- Avoid sharp objects such as ball-point pens, fingernails, etc.
- Only clean the touchscreen with a soft cloth that is lightly dampened with water or a mild cleaning solution. Follow the instruction given in Section 6.1 “Cleaning and disinfection of the instrument”.

WARNING!
5.1.2 *Meaning of the buttons / Navigation*

Software button, calls up appropriate function such as Memory or Menu

“UP” button, selects the next higher listed item or increases the numerical value

“DOWN” button, selects the next lower listed item or decreases the numerical value

“ESC” button, leaves the menu screen or rejects changes

“OK” button, selects the next lower menu screen or confirms a selection

Shows a button that is inactive

5.2 *Memory – (data storage)*

The instrument is equipped with data storage, which can store up to 100 results.

5.2.1 *Displaying results from memory*

Access to the data storage is possible only if the photometer is in the ready mode.

Illustration 25: Display screen, ready mode.
Further functions

Press this button to display the measured data store.

You will see the following screen display, for example:

Illustration 26: Display screen, data storage, result #22.

The entry displayed is the most recently result, which is simultaneously the uppermost entry in the list of results.

Press this button to display preceding results until you reach the first entry on the list.

Press this button to display successive results, until you reach the last entry on the list (current result).

Press this button (Escape) to leave the measured data store.

Press this button to select the menu “Options”. In this menu you will find additional functions for printing out and for erasing results. Further information in this regard can be found in Sections 5.2.2 and 5.2.3.
Further functions

If correlation is activated (see Section 5.3.1 “Information about the photometer”) you may see - - - or +++ symbols at any positions in the data storage. This indicates that the real results cannot be shown with the current settings of the correlation function, because they exceed the testing range.

If the estimated Hematocrit mode has been activated the hematocrit result will be displayed as well. See Section 5.3.8.1 “Output activation of hematocrit value”.

5.2.2 Printing out results

In order to print out from data storage you must have a printer connected. Instructions for this can be found in Section 5.4 “Standard print mode” and Section 5.5 “Expanded print mode”.

You can print out results as follows:

- From the data storage display press the button Options.

- Select the entry “Print” using the buttons.

- Confirm the selection with OK, to print out the results, otherwise press ESC, in order not to print.

Printing out the results can take a few seconds. Following printing, the photometer changes back again to display the data storage.

5.2.3 Deleting the stored test data

With this function the entire data storage (all results) is deleted.

To erase the data storage, proceed as follows:

- From the data storage display press the button Options.
Further functions

- Select the entry “Erase” using the buttons.
- Confirm the selection with OK, to delete the data storage, otherwise press ESC, in order not to delete.

**Tip**

Following deleting, the instrument changes back again to display measured data storage.

5.3 Menu functions

The photometer has various possible settings that can be accessed through the menu function.

Access to the menu is possible only if the photometer is in the ready mode.

Illustration 27: Display screen, ready mode.

Press this button to access the Menu.

You will see the following screen display:
Further functions

Illustration 28: Display screen, Menu.

Press this button to select previous menu entries, until you reach the first entry.

Press this button to select succeeding menu entries, until you reach the last entry.

Press this button to select the next higher menu level to leave the menu.

Press this button to select the next lower menu level, to adjust settings, or to display information.

5.3.1 Information about the photometer

Information about the photometer and the status of various components can be found under the menu item "Info". This information is partly needed for servicing.

You can scroll up or down with the arrow buttons.

With this button you can leave the information display again.

The following information is displayed:
- Total number of test results
Further functions

- Number of tests today
- Number of tests run using battery power
- Remaining battery charge
- Model and serial number
- Version number of the firmware
- Correlation function to conform the output of results with different devices and/or methods

\[ y = m \cdot x + n \]

- \( m \) ... correlation factor
- \( n \) ... offset

if \( m = 1 \) and \( n = 0 \) (factory defaults) the function is not active

The correlation can only be enabled by authorized personnel on special request. Contact Stanbio Laboratory’s Technical Service Department for additional information.

- SPN, the current Service Process Number, needed by Servicing

5.3.2 Setting the date

The function of setting the current date can be found under the “Format” menu, sub-menu “Date Format”. Setting the date is important for the correct relationships of the results from the data storage (memory) or for printing out the results.

The format to enter the date depends on the date format setting. (see Section 5.3.7.2 “Setting date format”)

The arrow buttons increase or decrease the numerical value in each case.

Press this button to reject the entry and to leave the adjustment.
Further functions

Press this button to confirm the current setting and to access the next entry. After entering the last value, the settings are stored and you leave the adjustment menu.

5.3.3 Setting the time

The function of setting the photometer to the current time can be found under the “Format” menu, sub-menu “Time Format”. Setting the time is important for the correct relationships of the results from the data storage (memory) or for printing out the results.

The format to enter the time depends on the time format setting. (see Section 5.3.7.3 “Setting time format”)

The functions of the individual buttons can be found in Section 5.3.2 “Setting the date”.

5.3.4 Setting the units

The function of setting the units can be found under the “Option” menu, sub-menu “Unit”. This gives you the ability to set the test unit for the hemoglobin value you wish to use. This setting influences all test displays, including the results in the data storage (memory) and the printer.

Illustration 29: Display screen, Units.
Further functions

You can select the following units:
- mmol/L
- g/dL (default)
- g/L

Select the appropriate entry using the arrow buttons.

Press this button to reject the selection.

Press this button to confirm the selection.

5.3.5 Hgb-limits
The function of setting the Hgb limits can be found under the "Option" menu, sub-menu "Range". This gives you the ability to set the test unit for the hemoglobin value you wish to use. This setting influences all test displays, including the results in the data storage (memory) and the printer.

Limits can be set for the following groups of patients:
- Adult Male - (13 - 18 g/dL) default
- Adult Female - (11 - 16 g/dL) default
- Child - (11 - 16 g/dL) default

Corresponding upper limits can be set within 5 - 25.5 g/dL (0.31 - 15.81 mmol/l), lower limits from 5 g/dL (0.31 mmol/l) up to the upper limit.

While the "Hgb-limits" mode is activated, the lower limits must show different values than the upper limits of all groups of patient. Otherwise the "Hgb-limits" mode will be inactive.

5.3.6 Setting the display contrast
The LCD display contrast is strongly dependent for technical reasons on the environmental temperature. You can set the
contrast via the Menu item “Contrast” according to your preference.

Please be very careful when setting the contrast. At certain temperatures you can no longer read anything on the display under certain conditions with some contrast settings. Should you accidentally store these settings by pressing the OK key, the instrument must be reset. You can read about this in Section 7 “Troubleshooting”.

The function of the individual keys can be found in Section 5.3.2 “Setting the date”.

5.3.7 Settings

In this menu some general format settings can be found.

5.3.7.1 Setting the language

The HemoPoint® H2 photometer supports various national languages. The function of setting the language can be found under the “Format” menu, sub-menu “Language”. This gives you the ability to set the photometer to the language you wish to use.

The following languages are supported:

- English (default)
- German
- Spanish

The function of the individual keys can be found in Section 5.3.4 “Setting the units”.

5.3.7.2 Setting date format

Under the “Format” menu, sub-menu “Date Format” the output format of the date can be set. This affects the output of data record in the data storage (memory) and the printout of the results.

The following settings are supported:

- DD.MM.YY (Day.Month.Year)

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Further functions

- MM/DD/YY (Month/Day/Year) (default)
- DD/MM/YY (Day/Month/Year)
- YY-MM-DD (Year-Month-Day)

5.3.7.3 Setting time format
Under the “Format” menu, sub-menu “Time Format” the output format of the time can be set. This affects the output of data records in the data storage and the printout of the results.

The following settings are supported:
- 12 hours (default)
- 24 hours

5.3.7.4 Setting the power frequency
Under the “Format” menu, sub-menu “Frequency” the frequency of the electrical current to be use can be set. In the United States 120v, 60 Hz is the norm.

The following settings are supported:
- 50 Hz
- 60 Hz (default)

The function of the individual keys can be found in Section 5.3.4 “Setting the units”.

5.3.8 Menu options
To keep the main menu clear, all functions that are used less frequently have been placed under the menu item “Options”.

5.3.8.1 Output activation of hematocrit value
Display of the approximate hematocrit value can be activated in the menu item "Hematocrit", which will be calculated of the hemoglobin value. This is done by using the formula Hct=F*Hb, with F= 0.301.

The use of this formula is allowed only within the normal hemoglobin range, means from 12.0 g/dL (7,44 mmol/l) – 18.0 g/dL (11,16 mmol/l). If the Hgb result is outside this range then the
estimated hematocrit result will not be calculated and symbol "N/A" will appear.

5.3.8.2 Setting the print mode
To print-out test result(s) and result(s) from the memory, the HemoPoint® H2 supports different print modes:

- Standard-Print Mode
- Expanded-Print Mode (default)

In standard-print mode you will get a simple and compact print out of the result memory store including all available information in list form.

In the expanded-print mode you have the possibility to separate single records and to assign them to patient records.

5.4 Standard print mode

5.4.1 Header

Stanbio Laboratory
www.stanbio.com

Version...: 1.06.0
Serial No.: 3003-03-0001
Cust.Service: (800) 531-5535
Tech.Service: (866) 782-6246

Hgb Limits:
Male.....: 13-18 g/dL
Female.: 11-16 g/dL
Child....: 11-16 g/dL

Printed one time a day, after changing the print mode or after changing the date.
5.4.2 Range mode (On), Hematocrit (On)

<table>
<thead>
<tr>
<th>No.</th>
<th>Date</th>
<th>Time</th>
<th>Hgb</th>
<th>Hct</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>01/01/03</td>
<td>12:03pm</td>
<td>15.0 g/dL</td>
<td>+F 51% E</td>
</tr>
<tr>
<td>2.</td>
<td>01/01/03</td>
<td>12:03pm</td>
<td>13.2 g/dL</td>
<td>+F 43% E</td>
</tr>
</tbody>
</table>

5.5 Expanded print mode

5.5.1 Header

Stanbio Laboratory
www.stanbio.com

Version...: 1.06.0
Serial No.: 3003-03-0001
Cust.Service: (800) 531-5535
Tech.Service: (866) 782-6246

Printed one time a day, after changing the print mode or after changing the date.

5.5.2 Range mode (On), Hematocrit (On)

Patient No.01 ___________________________(Female)
Date.............: 02/25/03
Time.............: 10:45am
Hgb.............: 11.9 g/dL (+) (13.0-18.0 g/dL)
Hct.............: 45% (Estimated)

5.5.2.1 Setting the tone signal
Further functions

Under the “Option” menu, sub-menu “Beeper” the signal can be switched ON or OFF. This adjustment affects the button signals as well as the signals that sound at the end of the current test.

5.5.2.2 Setting the stand-by time

The HemoPoint® H2 is equipped with integrated energy management. If the photometer is not used for a certain time, it switches into the Stand-by mode (see Section 3.3.4 "Stand-by mode"). Under this menu, you can set the number of minutes the photometer will remain active (ON), after which the instrument will switch into the Stand-by mode.

Under the “Option” menu, sub-menu “Stand by” the Stand-by time can be set according to your preference. Use the appropriate arrow key to either increase or decrease the stand-by time (in increments of 5 minutes).

Illustration 30: Display screen, Stand-by.

5.5.2.3 The history menu

This menu is intended to be used by authorized service personnel only. It is designed to give Stanbio’s technical service representative information that can help the customer to resolve testing or device problems.

Your Stanbio technical service representative will tell you how to handle this menu item if and when it is necessary.
Further functions

5.5.2.4 The service menu
The menu item “Service” is intended for an authorized Stanbio technical service representative only.

**WARNING!**

Please do not attempt to “crack” the 4 character Service Access Number (SAN); there is no sensible strategy for doing this. The number for authorized access changes itself automatically at short intervals.

5.5.3 Information on contacting us
The menu item “Contact” shows you how to contact Stanbio if you need further help or if you wish to place an order. Information on this can also be found in Section 10.2 “Further information”.

5.6 Connecting accessories
The HemoPoint® H2 photometer is equipped with a serial interface at the back of the instrument.

Illustration 31: Interface socket

**WARNING!**

Only instruments specifically intended for the purpose should be connected to this accessories socket, using the appropriate approved connecting leads. To avoid short circuits, keep sharp metallic objects away from the sockets.
5.6.1 Connecting a printer

The HemoPoint® H2 photometer supports the connection of a Seiko Model No. DPU-414 serial printer.

Illustration 32: DPU-414 printer.

The DPU-414 can be ordered through an authorized Stanbio Laboratory distributor.

With the use of a printer you can record the test results of each patient or later by printing out the data storage results. (see Section 5.2.2 “Printing out results”).

5.6.1.1 Connecting lead

To connect the printer to the HemoPoint® H2 a special printer lead is needed which likewise can be ordered through an authorized Stanbio Laboratory distributor.

Please only use the cable intended for this purpose, otherwise both the photometer and the printer may be seriously damaged.

WARNING!
Further functions

The printer cable is equipped at one end with a 9 pole USB-D plug to connect with the printer and at the other end with a 6 pole mini-DIN plug to connect to the interface socket of the HemoPoint® H2. (see illustration 33, Connecting the Seiko DPU-414 Printer)

Illustration 33: Connecting the Seiko DPU-414 printer.
6. Maintenance

6.1 Cleaning and disinfection of the instrument

6.1.1 Housing and touchscreen

It is essential here to pay attention to the instructions in Section 1.3 “Safety notes”.

Cleaning the housing and touchscreen is best accomplished with a lint-free cloth, lightly dampened with clean water. For more stubborn soiling, a mild soap solution may be used. For disinfection, standard solutions can be used for surface disinfection provided they do not contain alcohol or other solvent.

The housing is equipped with a high-quality lacquered surface. Please do not use any harsh cleaning agent or solvent otherwise the surface can be attacked and the photometer will look unsightly.

Before cleaning the touchscreen, open the cuvette holder. This blocks all the operational elements on the screen and no unintended entries can be made.

6.1.2 Cuvette holder

The cuvette holder can be removed from the instrument for cleaning. Proceed as follows:

- Open the cuvette holder until you feel a resistance and the holder will not extend further.
- Press down the silver pin on the left-hand side of the cuvette holder with a ball-point pen and draw the cuvette holder forward at the same time.
Illustration 34: Removing the cuvette holder.

The cuvette holder can now be cleaned with a mild soap solution. For disinfection, standard solvent-free preparations can be used similarly as for surface disinfection.

To replace the cuvette holder, simply push it in the correct position into the opening in the housing until it can be felt to engage.

**WARNING**

*Please wait until the cuvette holder is completely dry before replacing it.*

*Do not use any cleaning agent for cleaning the cuvette holder that could leave scratches on its surface.*

### 6.1.3 Optical unit

The optical unit is situated inside the photometer and has no direct contact with the cuvette therefore no routine cleaning is needed. Cleaning the optical unit can become necessary if the measured maximum light intensity of the photometric light source no longer achieves the appropriate level required for testing. Please read the appropriate section, Section 7 “Troubleshooting”.
For cleaning the optical unit the use of a special HemoPoint® H2 optics cleaner is recommended. The Optics Cleaner can be obtained through a Stanbio authorized distributor. Please follow the instructions for use that can be found in the package insert that comes with the Cleaner.

Cleaning the optical unit is a delicate operation inside the instrument. Please do not use any cleaning agents other than the original Stanbio Optics Cleaner.

**6.1.4 Power adaptor**

The power adaptor can be cleaned and disinfected in the same way as the instrument housing (see Section 6.1.1 “Housing and touchscreen”).

**Care! Danger of fatal electric shock!**

It is essential to heed the instructions in Section 1.3 “Safety notes”.

**6.2 Charging and care of the battery**

Your HemoPoint® H2 photometer is equipped with a NiMH (Nickel Metal Hydride) battery. The capacity of the battery is calculated on the basis of being sufficient for 100 hours of measuring operation. As with many other components, there is an underlying ageing process within the battery and it especially loses capacity over the course of time. Frequent partial discharging and recharging accelerates this process. By observing a few “golden rules” you can considerably influence the life span of the battery:

**6.2.1 Charging strategy**

To maintain the battery’s full capacity, the battery should always be discharged as far as possible before being recharged again.

To avoid restricting potential use, adequate protection to maintain the battery’s capacity cannot be installed. The instrument is therefore adjusted so that the battery will immediately recharge when it has only lost a small amount of charge when the instrument is connected to the power adapter.
To conserve the battery capacity, from time to time leave the instrument in battery operation mode until it is almost fully discharged.

Illustration 35: Display screen when battery is discharged.

6.2.2 Charging time

The battery charging time depends on the charge remaining and can be fully charged in 9 hours.

If you recharge it overnight, the battery will be fully charged and ready for use.

After recharging, it is not necessary to disconnect the photometer from the electrical connection. Overloading the battery is impossible.

6.2.3 Self discharge

Self-discharging is a typical property of batteries. Even when you are not using the instrument, the battery slowly discharges and later reaches the deeply discharged phase, which can damage the battery.

IMPORTANT! Fully charge the battery at least once a month.
6.3 Repairs

Care! Danger of fatal electric shock!
It is essential to follow the instructions in Section 1.3 "Safety notes".

If your instrument does not function as expected, e.g. if the measured results are not credible, or you are getting incorrect reports from the instrument, try to solve the problem initially with the aid of Section 7 "Troubleshooting".

If you cannot get any further, contact Stanbio’s technical service department.

6.4 Disposal management concept

It is the responsibility of the user to arrange proper disposal of the individual components.

- The microcuvettes and containers for potentially infectious solutions (Hemolysate, control bloods, etc.) must be disposed of in accordance with the regulations in force in your establishment.
- The HemoPoint® H2 photometer and electronic accessories must be disposed of according to the regulations for the disposal of electronic components, after removing the battery.
- The battery must be disposed of according to the regulations for the disposal of old batteries.
# 7. Troubleshooting

Before you call Stanbio's technical service department or send the instrument in for repair, please try to define or solve the problem with the help of this section.

### Care ! Danger of fatal electric shock !

*It is essential to follow the instructions in Section 1.3 “Safety notes”.*

---

## 7.1 Problem solving

<table>
<thead>
<tr>
<th>Display shows nothing.</th>
<th>“Awaken” the instrument by touching the touchscreen, opening / closing the cuvette holder, or plugging in the power adaptor. (see Section 3.3.4 'Stand-by mode”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Display contrast is too weak.</td>
<td>Perform a “Reset”. (see Section 7.2 “Resetting of the photometer”</td>
</tr>
</tbody>
</table>

| Display screen is black. | Perform a “Reset”. (see Section 7.2 “Resetting of the photometer” |

| Display screen is hard to read. | Reset the display contrast. (see Section 5.3.6 “Setting the display contrast” |

---

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
## Troubleshooting

### Instrument will not switch on.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery is discharged.</td>
<td>Plug in the power adaptor.</td>
</tr>
<tr>
<td>Software does not respond.</td>
<td>Carry out a “Reset”. (see Section 7.2 “Resetting of the photometer”)</td>
</tr>
<tr>
<td>Instrument does not react when connected to the power adaptor.</td>
<td>Check the connections and that all plug contacts are correctly seated.</td>
</tr>
</tbody>
</table>

### Instrument switches off too quickly or too slowly.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stand-by time is unsuitable.</td>
<td>Reset the Stand-by time. (see Section 5.5.2.2 “Setting the Stand-by time”)</td>
</tr>
</tbody>
</table>

### Instrument does not react to opening or closing the cuvette holder.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery is discharged. (Display shows nothing)</td>
<td>Connect the power adaptor.</td>
</tr>
<tr>
<td>Software does not react.</td>
<td>Carry out a “Reset”. (see Section 7.2 “Resetting of the photometer”)</td>
</tr>
</tbody>
</table>

### Instrument does not react to touching the touchscreen

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery is discharged. (Display shows nothing)</td>
<td>Connect the power adaptor.</td>
</tr>
<tr>
<td>No key field touched.</td>
<td>Touch a key on the touch screen which has a designated function.</td>
</tr>
<tr>
<td>There are no keys active in the current mode of the photometer.</td>
<td>Close the cuvette holder and await a possible measurement.</td>
</tr>
<tr>
<td>Software does not react.</td>
<td>Carry out a “Reset”. (see Section 7.2 “Resetting of the photometer”)</td>
</tr>
</tbody>
</table>

### Background illumination does not work

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power adaptor is not connected</td>
<td>Connect the power adaptor.</td>
</tr>
</tbody>
</table>
## Troubleshooting

### Signal tone does not work, or does not work properly.

<table>
<thead>
<tr>
<th>Issue Description</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tone signal is set incorrectly.</td>
<td>Adjust the signal tone. (see Section 5.5.2.1 &quot;Setting the tone signal&quot;)</td>
</tr>
</tbody>
</table>

### Display texts are not shown in your language.

<table>
<thead>
<tr>
<th>Issue Description</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language is set incorrectly.</td>
<td>Set your language. (see Section 5.3.7.1 &quot;Setting the language&quot;)</td>
</tr>
</tbody>
</table>

### Time displayed is incorrect.

<table>
<thead>
<tr>
<th>Issue Description</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time is set incorrectly.</td>
<td>Reset the time. (see Section 5.3.3 &quot;Setting the time&quot;)</td>
</tr>
</tbody>
</table>

### Date shown in the printout or data storage is incorrect or will not be displayed as expected.

<table>
<thead>
<tr>
<th>Issue Description</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date setting is incorrect.</td>
<td>Reset the date. (see Section 5.3.2 &quot;Setting the date&quot;)</td>
</tr>
<tr>
<td>Date format is set incorrectly.</td>
<td>Set the date format. (see Section 5.3.7.2 &quot;Setting date format&quot;)</td>
</tr>
</tbody>
</table>

### Time shown in the printout or measured data storage is incorrect or will not be displayed as expected.

<table>
<thead>
<tr>
<th>Issue Description</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time is set incorrectly.</td>
<td>Reset the time. (see Section 5.3.3 &quot;Setting the time&quot;)</td>
</tr>
<tr>
<td>Time format is set incorrectly.</td>
<td>Set the time format. (see Section 5.3.7.3 &quot;Setting time format&quot;)</td>
</tr>
</tbody>
</table>

### Incorrect units are shown.
### Troubleshooting

<table>
<thead>
<tr>
<th>Setting of units is incorrect.</th>
<th>Set the units of measurement. (see Section 5.3.4 “Setting the units”)</th>
</tr>
</thead>
</table>

**AC power adaptor symbol in the display is not shown.**

<table>
<thead>
<tr>
<th>AC power adaptor is not correctly connected.</th>
<th>Check the connections and that all the plug contacts are correctly seated.</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the current instrument mode the symbol is not updated.</td>
<td>Wait until the instrument is in ready mode.</td>
</tr>
</tbody>
</table>

**Battery symbol in the display is not shown.**

<table>
<thead>
<tr>
<th>Battery is defective.</th>
<th>Operation only possible using the AC power adaptor. Contact Stanbio Technical Support.</th>
</tr>
</thead>
</table>

**Battery does not charge.**

<table>
<thead>
<tr>
<th>AC power adaptor is not correctly connected.</th>
<th>Check the connections and that all the plug contacts are correctly seated.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery is still sufficiently charged</td>
<td>Check the symbol shown on the display.</td>
</tr>
</tbody>
</table>

**Display shows “Temp. too high “**

<table>
<thead>
<tr>
<th>Environment temperature outside the specified temperature range.</th>
<th>Operate the photometer in a cooler place.</th>
</tr>
</thead>
</table>

**Display shows “Temp. too low “**

<table>
<thead>
<tr>
<th>Environment temperature outside the specified temperature range.</th>
<th>Operate the photometer in a warmer place.</th>
</tr>
</thead>
</table>

**Display shows “Battery almost empty “**

<table>
<thead>
<tr>
<th>State of charge is &lt; 10% of the total capacity.</th>
<th>Recharge the battery as soon as possible.</th>
</tr>
</thead>
</table>
### Troubleshooting

#### Fault display “Battery error - Battery defect“
<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery state is outside its specification and it will be switched off.</td>
<td>Operation only possible using the AC power adaptor. Contact Stanbio Technical Support.</td>
</tr>
</tbody>
</table>

#### Fault display “Optics error – Intensity too low“
<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuvette holder is not correctly locked.</td>
<td>Check the cuvette holder. (see Section 6.1.2 “Cuvette holder“)</td>
</tr>
<tr>
<td>Optical unit is dirty.</td>
<td>Clean the optical unit. (see Section 6.1.3 “Optical unit“)</td>
</tr>
<tr>
<td>Environment temperature too high.</td>
<td>Operate the instrument within the correct specifications.</td>
</tr>
<tr>
<td>Optics defective.</td>
<td>Contact Stanbio Technical Support</td>
</tr>
</tbody>
</table>

#### Fault display “Optics error – Intensity too high“
<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment temperature too low.</td>
<td>Operate the instrument within the correct specifications.</td>
</tr>
<tr>
<td>Optics defective.</td>
<td>Contact Stanbio Technical Support</td>
</tr>
</tbody>
</table>

#### Fault display “Measurement Error - Timeout“,
- Repeated testing of one cuvette produces strongly fluctuating results,
- Results with control cuvette and external controls are outside the stated limits of tolerance,
- Results are not credible.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuvette defective / optical eye is soiled / air bubbles</td>
<td>Test with the control cuvette. Use a new microcuvette (from a new container if necessary) and repeat the test. (see Section 4 “Sampling and testing procedure”)</td>
</tr>
<tr>
<td>False type of blood</td>
<td>Use human blood. (see Section 8.1 “HemoPoint® H2 photometer”)</td>
</tr>
</tbody>
</table>
## Troubleshooting

<table>
<thead>
<tr>
<th>Issue</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuvette holder is not correctly locked into place.</td>
<td>Check the cuvette holder.</td>
</tr>
<tr>
<td></td>
<td>(see Section 6.1.2 &quot;Cuvette holder&quot;)</td>
</tr>
<tr>
<td></td>
<td>Measure with the control cuvette.</td>
</tr>
<tr>
<td>Optical unit is dirty.</td>
<td>Clean the optical unit.</td>
</tr>
<tr>
<td></td>
<td>(see Section 6.1.3 &quot;Optical unit&quot;)</td>
</tr>
<tr>
<td></td>
<td>Measure with the control cuvette.</td>
</tr>
<tr>
<td>AC power frequency set incorrectly</td>
<td>Set the correct AC power frequency in the Menu.</td>
</tr>
<tr>
<td></td>
<td>(see Section 5.3.7.4 &quot;Setting the electrical power frequency&quot;)</td>
</tr>
<tr>
<td></td>
<td>Measure with the control cuvette.</td>
</tr>
<tr>
<td>Unsuitable environment</td>
<td>Pay attention to the instructions for setting up the photometer.</td>
</tr>
</tbody>
</table>

### Fault display “Measurement Error – Value too low“

<table>
<thead>
<tr>
<th>Issue</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample concentration too low or false type of sample.</td>
<td>Observe the measuring range. Use human blood.</td>
</tr>
<tr>
<td></td>
<td>(see Section 8.1 “HemoPoint® H2 photometer”)</td>
</tr>
</tbody>
</table>

### Fault display “Measurement Error – Value too high“

<table>
<thead>
<tr>
<th>Issue</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample concentration too high or false type of sample.</td>
<td>Observe the measuring range. Use human blood.</td>
</tr>
<tr>
<td></td>
<td>(see Section 8.1 “HemoPoint® H2 photometer”)</td>
</tr>
<tr>
<td>Unsuitable sampling.</td>
<td>Fill cuvette in one step.</td>
</tr>
<tr>
<td></td>
<td>(see Section 4 “Sampling and testing procedure”)</td>
</tr>
<tr>
<td>Defective cuvette.</td>
<td>Test with the control cuvette.</td>
</tr>
<tr>
<td></td>
<td>Use a new microcuvette (from a new container if necessary) and repeat the measurement.</td>
</tr>
<tr>
<td></td>
<td>(see Section 4 “Sampling and testing procedure”)</td>
</tr>
</tbody>
</table>
## Troubleshooting

### Measurements are displayed during blank measurement.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuvette holder is not correctly locked.</td>
<td>Check the cuvette holder.</td>
</tr>
<tr>
<td></td>
<td>(see Section 6.1.2 &quot;Cuvette holder&quot;)</td>
</tr>
<tr>
<td></td>
<td>Measure with the control cuvette.</td>
</tr>
<tr>
<td>Optical unit is dirty.</td>
<td>Clean the optical unit.</td>
</tr>
<tr>
<td></td>
<td>(see Section 6.1.3 &quot;Optical unit&quot;)</td>
</tr>
<tr>
<td></td>
<td>Measure with the control cuvette.</td>
</tr>
</tbody>
</table>

### Printer does not print

<table>
<thead>
<tr>
<th>Issue</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect type of printer.</td>
<td>Connect to a DPU-414 printer.</td>
</tr>
<tr>
<td></td>
<td>(see Section 5.6.1 &quot;Connecting a printer&quot;)</td>
</tr>
<tr>
<td>Printer not &quot;online&quot;.</td>
<td>Switch the printer to online mode.</td>
</tr>
<tr>
<td></td>
<td>(see operating instructions for the printer)</td>
</tr>
<tr>
<td>Incorrect, or incorrectly connected, printer cable.</td>
<td>Use an original printer cable from Stanbio or check that the plug contacts are correctly seated.</td>
</tr>
<tr>
<td></td>
<td>(see Section 5.6.1.1 &quot;Connecting lead&quot;)</td>
</tr>
</tbody>
</table>
7.2 Resetting of the photometer

The "Reset" serves to transfer the instrument into a defined mode, without changing user-specific settings significantly. The settings for contrast, date and time are lost, however.

The reset button can be found on the underside of the instrument.

Illustration 36: Location of the reset button.

To reset the instrument, simply press the button using a narrow object such as a ballpoint pen.

Illustration 37: Confirmation display, Reset.
8. **Technical data**

8.1 **HemoPoint® H₂ photometer**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measuring procedure</td>
<td>Optical absorption photometry</td>
</tr>
<tr>
<td>Source</td>
<td>Dual-Color-LED 570 / 880 nm</td>
</tr>
<tr>
<td>Dominant wavelength of source</td>
<td>1ᵉʳ wavelength: 570 ± 5 nm, 2ᵈʳ wavelength: 880 ± 10 nm</td>
</tr>
<tr>
<td>Spectral half value width of the source</td>
<td>1ᵉʳ wavelength: 15 ± 3 nm, 2ᵈʳ wavelength: 50 nm</td>
</tr>
<tr>
<td>Receiver</td>
<td>Photodiode 350 – 820 nm</td>
</tr>
<tr>
<td>Measuring range</td>
<td>0 – 25.6 g/dL</td>
</tr>
<tr>
<td>Sample material</td>
<td>Venous, arterial, or capillary human blood</td>
</tr>
<tr>
<td>Sample carrier</td>
<td>Stanbio Microcuvette</td>
</tr>
<tr>
<td>Sample size</td>
<td>10 µL</td>
</tr>
<tr>
<td>Linearity</td>
<td>0- 20.0 g/dL ± 0.3 g/dL, &gt;20.0 g/dL ± 0.7 g/dL</td>
</tr>
<tr>
<td>Measuring time</td>
<td>Dependent on concentration, 10 – 180s</td>
</tr>
<tr>
<td>Data storage (memory)</td>
<td>Up to 100 results, including date and time</td>
</tr>
<tr>
<td>Dimensions (LxWxH)</td>
<td>6.25 in. x 6.5 in. x 2.5 in.</td>
</tr>
</tbody>
</table>
### Technical data

| Weight | 1.3 lbs. |
| Power supply | AC Power adaptor: |
| | Input: 100-250 V AC / 50-60Hz |
| | Output: 6 VDC |
| Integrated battery: | Voltage: 2.4 V |
| | Capacity: 1500 mAh |
| | (ca. 100 h operation time) |
| Power take up | maximal: 3 W |
| | typically: 1.2 W |
| | minimal: 30 mW |
| Interface | Printer (RS 232 C) |
| Environmental temperature | Room temperature (15 – 30°C) |

### 8.2 Microcuvette

| Type | Microcuvette, coated with reagents for determining the hemoglobin in venous, arterial, or capillary blood |
| Volume in the cuvette cavity | 10 μl |
| Reagents | Sodium desoxycholate, sodium nitrite, sodium azide, non-reactive additives. |
| Material | Polystyrene |
| Storage | Room temperature (15 – 30°C), dry storage in the original containers |
| Dimensions (LxWxH) | 1.5 in. x 1.0 in. x 0.125 in. |
9. Reference range

9.1 Normal range

Different blood hemoglobin values have been reported in the literature (1,2,3,4).

**Adult Males:** 13.0 – 18.0 g/dL

**Adult Females:** 11.0 – 14.0 g/dL

**Children (2 yrs to teenage):** 10.0 – 18.0 g/dL

**Infants (post-natal):** 10 – 14 g/dL

The highest Hgb concentrations are usually measured in neonates.

Due to the wide range of conditions (dietary, geographical, smoking, exercise, recumbency, etc.), which affect reference values, it is recommended that each laboratory establish its own expected ranges.

9.2 Understanding your result

Hemoglobin is the oxygen-carrying pigment and main component of red blood cells. Low hemoglobin levels may indicate anemia, recent hemorrhage or fluid retention. Elevated hemoglobin levels may indicate hemoconcentration from polycythemia or dehydration.

10. Appendix

10.1 List of replacement parts and consumer materials

<table>
<thead>
<tr>
<th>Article No.</th>
<th>Description</th>
<th>Ordering unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>3010-100</td>
<td>HemoPoint® H2 Microcuvettes</td>
<td>1 kit</td>
</tr>
<tr>
<td></td>
<td>2 Containers @ 50 cuvettes each (100 tests)</td>
<td></td>
</tr>
<tr>
<td>3010-200</td>
<td>HemoPoint® H2 Microcuvettes</td>
<td>1 kit</td>
</tr>
<tr>
<td></td>
<td>4 Containers @ 50 cuvettes each (200 tests)</td>
<td></td>
</tr>
<tr>
<td>3060-601</td>
<td>Hemoglobin Controls</td>
<td>1 set</td>
</tr>
<tr>
<td></td>
<td>Set of 6 dropper bottles 1 mL :</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 x Hgb control-low, 1 x Hgb control -normal</td>
<td></td>
</tr>
<tr>
<td>3050-005</td>
<td>HemoPoint® H2 Cleaner</td>
<td>1 set</td>
</tr>
<tr>
<td></td>
<td>For cleaning the optical unit, Set of 5 Cleaner</td>
<td></td>
</tr>
<tr>
<td>3020-001</td>
<td>HemoPoint® H2 Control Cuvette</td>
<td>1 pc.</td>
</tr>
<tr>
<td></td>
<td>For check of HemoPoint® H2 meter (serial # specific)</td>
<td></td>
</tr>
<tr>
<td>G3100-001</td>
<td>Printer, DPU-414</td>
<td>1 pc.</td>
</tr>
<tr>
<td></td>
<td>Thermal printer (serial interface) w/adaptor</td>
<td></td>
</tr>
<tr>
<td>3040-001</td>
<td>Printer, Power Adaptor</td>
<td>1 pc.</td>
</tr>
<tr>
<td>3175-001</td>
<td>Printer, Battery Pack</td>
<td>1 pc.</td>
</tr>
<tr>
<td></td>
<td>Rechargeable battery pack for DPU-414 printer</td>
<td></td>
</tr>
<tr>
<td>3170-001</td>
<td>Printer, Lead</td>
<td>1 pc.</td>
</tr>
<tr>
<td></td>
<td>For connecting the DPU-414 to the HemoPoint® H2 photometer</td>
<td></td>
</tr>
<tr>
<td>3180-005</td>
<td>Printer, Thermal Paper</td>
<td>1 set</td>
</tr>
<tr>
<td></td>
<td>Suitable for DPU-414, Set consists of 5 rolls</td>
<td></td>
</tr>
<tr>
<td>3030-001</td>
<td>HemoPoint® H2 Cuvette Holder</td>
<td>1 pc.</td>
</tr>
<tr>
<td>3050-001</td>
<td>Power Adaptor U.S.A.</td>
<td>1 pc.</td>
</tr>
<tr>
<td></td>
<td>for HemoPoint® H2</td>
<td></td>
</tr>
<tr>
<td>G3000-001</td>
<td>HemoPoint® H2 Photometer</td>
<td>1 pack</td>
</tr>
<tr>
<td>3060-001</td>
<td>Carrying Case, Plastic</td>
<td>1 pc.</td>
</tr>
<tr>
<td></td>
<td>for HemoPoint® H2 photometer, power adaptor, microcuvettes, control cuvettes</td>
<td></td>
</tr>
<tr>
<td>3071E-001</td>
<td>Users’s Guide - English</td>
<td>1 pc.</td>
</tr>
<tr>
<td></td>
<td>for HemoPoint® H2 photometer</td>
<td></td>
</tr>
<tr>
<td>3071S-001</td>
<td>User’s Guide - Spanish</td>
<td>1 pc.</td>
</tr>
<tr>
<td></td>
<td>for HemoPoint® H2 photometer</td>
<td></td>
</tr>
</tbody>
</table>
10.2 Further information

If you have any questions over and above this user's guide, we would be pleased to help. Here is all the important contact information:

**Main address:** Stanbio Laboratory 1261 North Main Street Boerne, Texas 78006 U.S.A.

**Telephone:** (830) 249-0772

**Fax:** (830) 249-0851

**Technical Support:** (800) 531-5535

**e-Mail:** stanbio@stanbio.com

**Internet:** www.stanbio.com
## 11. Index

### A

- accessories • 5, 42, 43, 47, 50, 57
- air bubbles • 20
- azide methemoglobin method • 63

### B

- battery • 10, 11, 13, 36, 48, 49, 50, 54, 60
- battery operation • 13
- blank reading • 26

### C

- calibration • 68
- charging • 48
- charging strategy • 48
- charging time • 49
- cleaning and disinfection of the instrument • 46
- concentration • 8, 15, 16, 24, 59, 62, 63, 65, 66, 67, 68, 69
- control blood • 28
- control cuvette • 26
- control solution • 28
- cuvette holder • 7, 10, 13, 21, 22, 23, 24, 25, 26, 27, 28, 30, 46, 47, 51, 52, 55, 56, 67
- cyanmethemoglobin method • 63

### D

- date • 37, 40, 53, 57
- display contrast • 38, 51
- disposal management concept • 50

### E

- environmental temperature • 60
- extinction • 16, 64, 65, 67, 68

### I

- incorrect measurements • 20
- intendend use • 8
- interface • 42, 60
- in-vitro diagnostic • 8

### K

- key • 31

### L

- laboratory reference methods • 62
- language • 39, 53
- linearity • 59
## Index

### M
- mains operation · 11
- maintenance · 46
- measured data store · 32, 60
  - deleting · 34
- measurement · 23
- measuring cycle · 25
- measuring procedure · 15, 59
- measuring process · 63
- measuring range · 59
- measuring time · 24, 59
- menu functions · 35
- Microcuvette · 15, 59, 60
- moisture · 15

### R
- reference range · 62
- repairs · 49
- Reset button · 57
- results
  - displaying · 32
  - printing · 33

### S
- safety notes · 5
- sample carrier · 59
- sample material · 59
- sample size · 59
- sampling procedure · 16
- self discharge · 49
- service
  - menu · 40
  - setting up · 9
- sodium azide · 63
- sodium desoxycholate · 63
- sodium nitrite · 63
- Soft-Reset · 57
- standard order pack · 9
- stand-by · 13, 40, 51
- storage · 61
- symbols
  - Danger symbol · 5
  - Tip symbol · 5
  - Warning symbols · 5

### T
- time · 37, 53, 57
- tone signal
  - adjusting · 40
- touchscreen · 30

---

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
transmission · 64, 65, 66, 67
troubleshooting · 51

V

Vanzetti · 63

units · 8, 25, 38, 53, 68
Exhibit 3.2

HemoPoint® H2 Cuvette Package Insert
Intended Use

Quantitative determination of hemoglobin in arterial, venous, or capillary blood. For in vitro diagnostic use. The HemoPoint® H2 system is intended to be used for the quantitative determination of hemoglobin (Hb) concentration in human blood. It consists of a photometer instrument and individual single-use microcuvettes filled with reagents. Using the microcuvette, a small amount of arterial, venous or capillary blood is taken up by capillary action. The microcuvettes are intended to be used once only and must be disposed of after use as potentially infectious waste, in accordance with the current regulations applicable to your establishment.

The HemoPoint® H2 system is designed for use in medical practices and in clinical laboratories to assist in medical diagnostic investigations. In addition it can be used in emergency and intensive care units and in medical facilities such as blood donor sessions and blood banks.

Blood sampling and operating the HemoPoint® H2 system should be carried out exclusively by clinically trained personnel with sound knowledge of the handling of in vitro diagnostic instruments and of this system.

HemoPoint® H2 cuvettes can also be used in combination with other compatible photometers.

Explanation and Summary of the Test

The recognized reference method for Hb determination (Hb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanamenoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the Hb concentration.

In 1955, Vanzetti suggested to replace KCN by NaCN and thus he "was able to reduce the toxicity of the reagent mixture considerably".

Vanzetti's method is also known as the azide methemoglobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system. In the HemoPoint® H2, however, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood.

The microcuvette is inserted into the HemoPoint® H2 photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb level is calculated and displayed.

Principle of Procedure

The Measurement Technique

In the HemoPoint® H2 photometer the light transmitted through the cuvette sample is measured.

Principle of photometric transmitted light measurement:

\[ P_0 \text{ % - light intensity, } P \text{ remaining light intensity, } b \text{ distance through the solution} \]

For this purpose, light is directed through the blood sample and the transmission T is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using Lambert-Beer's Law.

Light emitting diodes (LED's) are used as light sources and a photodiode to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

The Microcuvette

The plastic microcuvette consists of a clear body with a cavity which takes up approx. 10 μl of blood which combines with dry reagent chemistry. The optical distance between the cuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples.

The Chemistry Principle

In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary: sodium desoxycholate dissolves and disperses the cell walls of the red blood corpuscles. Hence the hemoglobin formerly contained in the erythrocytes is now available free in the solution.

The bivalent iron of the oxyhemoglobin and the desoxyhemoglobin becomes oxidized by sodium nitrite NaNO₂ to trivalent iron, in methemoglobin.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
Existing and formed methemoglobin and azide ions from sodium azide \( \text{NaN}_3 \) form a colored complex which exhibits maximal absorption at 540 and 575 nm and hence it can be quantitatively determined photometrically.

Illustration 1: Scheme of the reaction in determining hemoglobin using the azide methemoglobin method.

**Reagents**

- Approximately 40% w/w sodium deoxycholate
- Approximately 20% w/w sodium azide
- Approximately 20% w/w sodium nitrite
- Approximately 20% w/w non-reactive ingredients

**Warnings and Precautions**

Microcuvettes are designed only for in-vitro diagnostics! The reagents which coat the inner walls of the cuvettes are harmful and must not be swallowed. Wear suitable protection (gloves) at all time when handling blood samples. Please note that all human blood samples or products must be handled as potential infectious waste per your local regulations.

**Storage**

Store HemoPoint® H2 cuvettes at a temperature of 15°C - 30°C (59-86°F) at a dry place. Do not use a refrigerator for storage. Use cuvettes within 3 months after opening.

**Handling the HemoPoint H2 cuvettes**

Store the microcuvettes solely in the original container at room temperature. Only remove one microcuvette at a time from the container and then immediately close the lid again. Make sure that the lid is completely closed by pressing the lid firmly. The microcuvettes are analyzed optically in the HemoPoint® H2 photometer. Measurement light must pass through the sample cuvette to the photo detector with the least possible interference. Therefore it is crucial not touch the optical eye of the cuvette with fingers or dirty or sharp objects.

**Directions for use**

**Sample collection and preparation**

The HemoPoint® H2 Photometer can be used with capillary, venous, or arterial blood. Venous and arterial blood samples may be used if the blood collected is not more than 24 hours old and the samples have been stored refrigerated (2-8 °C). Prepare stored samples for measurement as follows:

- Remove sample tube from the refrigerator and bring to room temperature.
- Mix the sample well. (e.g. by a mechanical rotator or hand inversion)

Refer to the HemoPoint® H2 Operator’s Manual (or manual of a compatible instrument) for proper use of the instrument.

**Materials provided**

- HemoPoint® H2 Cuvettes

**Materials required but not provided**

- HemoPoint® H2 photometer or other compatible photometer
- HemoPoint® H2 Control cuvette
- In case of using commercial blood controls, use controls recommended by Stanbio Laboratory only.
- Lint-free material, e.g. gauze or Kleenex®

**Instructions for use**

**For capillary samples**

- Take out a cuvette from the supply container and close it again tightly.
- Make sure that your patient is sitting comfortably. There should be a good blood circulation in the hand from which you wish to take blood, i.e. it should be warm and relaxed.
- Lightly massage the fingers, in order to stimulate the circulation.
Disinfect the puncture site and allow to dry.

Press lightly on the finger tip and puncture with a suitable lancet from the side.

Rinse away the first drops of blood then, if necessary, press gently once again to get a drop of blood which is large enough to fill the cuvette completely. Avoid "milking" the finger.

Hold the tip of the cuvette in the middle of the dropper and let the cavity fill in one step.

In order to avoid contamination of the cuvette holder, please remove surplus blood from the outside of the cuvette. The cuvette sample prepared in this way can now be measured immediately or within 10 minutes at the latest. Please follow the instruction manual of the instrument.

For venous or arterial samples:

- Take out a cuvette from the supply container and close it again lightly.
- Remove sample tube from the refrigerator to bring to the ambient temperature.
- Stir the sample well during tempering. (e.g. by a mechanical rotator)
- Take out a cuvette from the supply container and close it again tightly.
- Pipette a sufficient drop of blood on a non-absorbent material. (e.g. plastic film)
- Contact the tip of the cuvette with the drop of blood and wait until the cuvette is filled completely. Do not refill the cavity.
- In order to avoid contamination of the cuvette holder, please remove surplus blood from the outside of the cuvette. The cuvette sample prepared in this way can now be measured immediately or within 10 minutes at the latest. Please follow the instruction manual of the instrument.

Limitations of the procedure:

- The cuvette sample can be measured immediately or within 10 minutes at the latest, otherwise false results may be obtained.
- In case of air bubbles to be seen in the optical eye caused by inadequate filling the cavity the readings may be false. In that case discard the cuvette and fill a new one using a new blood sample.
- Ensure that you do not hold the cuvette at its filling end, because it may contaminate the optical eye. In order to avoid contamination of the cuvette holder, please remove surplus blood from the outside of the cuvette.
- All results above 23.5 g/dl or equivalent must be confirmed by laboratory method.
- Sulfhemoglobin cannot be measured by this method.

Expected values:

The following hemoglobin values are considered normal:

- Adult males: 13.0 - 18.0 g/dl
- Adult females: 11.0 - 14.0 g/dl
- Infants (postnatal): 10.0 - 14.0 g/dl

Note! Children from 2 years to adolescence, gradual increase to adult norms. Due to a wide range of conditions which effect normal values, it is recommended that each laboratory establish its own "normal" range.

Quality control:

Daily check of the system can be done by using the Control Cuvette, provided with the instrument. In case additional quality control checks are required for regulatory reasons, all commercially available controls can be used. Please check if these controls are recommended by Stanbio Laboratory. Do not use Cyanmethemoglobin standards with this test.

Results:

The test result is displayed directly on the screen in the unit set before. The results are also stored in the built-in memory or can be printed-out. In case the result is above 25.6 g/dl or equivalent, "value too high" is displayed.

Specific performance characteristics:

Precision:

Technical Data:

Within-run precision on HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue Device ±2%

Experimental Data:

The precision evaluation experiment has been carried out in accordance with NCCLS EP5-A. On each of 20 testing days two separate runs with duplicate measurements within each run were carried out. 3 commercially available control materials were used.

The test was carried out using:

- 6 HemoPoint® H2 devices
- 2 HemoCue devices
- 16 lots of HemoPoint® H2 microcuvettes
- 3 operators.

3 - 77
### HemoPoint® H2 Cuvette Proposed Package Insert

#### Technical Data:

**Correlation Study:**

- **Correlation coefficient HemoPoint® H2 System compared to NCCLS H15-A3 reference method, venous blood:**
  - \( r = 0.98 \)

- **Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to HemoCue System, venous blood:**
  - \( r = 0.97 \)

#### Experimental Data:

- **HemoPoint® H2 System:**
  - (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device)
  - Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood:
    - \( Y = 0.023 + 1.006X \)
    - \( R = 0.999 \)
    - \( N = 174, \) duplicate measurements
    - Range 3.31 g/dL to 24.4 g/dL
    - (Summary from measurements at 4 Clinical study sites)

- **HemoPoint® H2 cuvettes measured in HemoCue device:*
  - Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood:
    - \( Y = 0.139 + 0.986X \)
    - \( R = 0.999 \)
    - \( N = 286, \) duplicate measurements
    - Range 3.25 g/dL to 23.85 g/dL
    - (Summary from 4 Clinical Study Sites)

---

**Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118**
Bibliography

3. HemoPoint® H2 Hemoglobin measuring system Operator’s Manual, Stanbio Laboratory, Boerne, Texas USA

HemoCue® is a registered trademark of HemoCue AG, Angelholm Sweden
Exhibit 3.3

HemoPoint® H2 Cuvette Tube Label
HemoPoint™ H2
50 Hemoglobin Cuvettes

For Use with HemoPoint™ H2 Meter
and HemoCue® Meter*

Contents: 50 Single-Use Hgb cuvettes

For In Vitro Diagnostic Use

Store at 15 - 30°C

CAT. NO. 3011-050

LOT NO. 031102 EXP: MAY 04

Use within 90 days of date opened.

Date Opened

* HemoCue® is a registered trademark of HemoCue, Angelholm, Sweden.

STANBIO LABORATORY • 1261 North Main • Boerne, TX USA 78006
1. General Description of Indication and Application

1.1. Hemoglobin Measurement as a Diagnostic Test

Hemoglobin measurement is a diagnostic test to assess the level of hemoglobin in blood. It is used in medical practices and in clinical laboratories to assist in medical diagnostic investigations. The test result is used for assessing the status of a patient in such clinical situations as hemorrhage, hemolysis, dehydration, and other shifts in plasma volume and for verifying the results of transfusion or treatment of other deficiency states such as malnutrition. The assay of hemoglobin is also used as a part of a general health screen, e.g., of prospective blood donors and women’s and children’s health.

Blood sampling and operating the HemoPoint® H2 system should be carried out by clinically trained personnel with knowledge of the handling of blood products and of the system. Based on the regulatory history of similar devices, this test may be CLIA waived.

1.2. Hemoglobin Measurement with the HemoPoint® H2

The HemoPoint® H2 system is intended to be used for the quantitative determination of hemoglobin (Hb) concentration in human blood. It consists of a tabletop photometer and individual single-use microcuvettes filled with dry reagents.

To use the microcuvette, a small amount of arterial, venous or capillary blood is taken up by capillary action. The filled cuvette is inserted into the HemoPoint® H2 photometer- the color produced by the chemical reaction in the cuvette is measured, and the hemoglobin level is displayed by the instrument. The microcuvettes are intended to be used once only and must be disposed of after use as potentially infectious waste.

1.3. HemoPoint® H2 in comparison to the predicate device, the Hemo_Cue

The operating principle (as further described below) of the HemoPoint® H2 system is functionally identical to the HemoCue B-Hemoglobin measurement system, which has been offered successfully in the USA for nearly 20 years. The HemoPoint® H2 microcuvettes are designed to function in HemoCue hemoglobin measurement instruments. (Section 5, Comparative Information, provides test results to substantiate this).

1.4. Estimation of Hemocrit

The HemoPoint® H2 is capable of estimating Hematocrit in normal subjects via user selectable option. Estimation is based on MCHC (mean cell hemoglobin concentration), a well known ratio between hemoglobin and hematocrit which is in the range of 30 to 35 g/dl in normal subjects. Estimated hematocrit is not intended to be indicative of disease states such as anemia, and device labeling so states this. Further, hematocrit values outside the measured hemoglobin range of 120 to 180 g/liter (12.0 to 18.0 g/deciliter) are not reported. Estimation of hematocrit is useful in screening applications such as blood donor clinics.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
2. Theory of Operation

2.1. Reference range

The physiological concentration of the total hemoglobin is specific for age and sex

- Women: 12.0 - 16.0 g/dl (g/dl - gram hemoglobin per deciliter of blood)
- Men: 13.0 - 17.5 g/dl
- Children, depending on age: 9.0 - 24.0 g/dl.

The highest Hb concentrations are measured in neonates.

2.2. Laboratory reference methods

The internationally recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolyzed and the bivalent iron in oxy- and deoxyhemoglobin are oxidized by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

2.3. Measuring method used in the HemoPoint® H2

In 1966, Vanzetti suggested the use of the reagents of the cyanmethemoglobin method K3[Fe(CN)6] (potassium hexacyano-ferrate(III)) and KCN to replace NaN02 and NaN3 and thus he was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti’s method is also known as the azide methemoglobin method.

In the HemoPoint® H2, (and similarly in the predicate HemoCue device), the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood.
2.4. Measuring process

2.4.1. Reaction in the microcuvette

In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary:

- **sodium desoxycholate** dissolves and disperses the cell walls of the red blood corpuscles. Hence the hemoglobin formerly contained in the erythrocytes is now available free in the solution.

![Diagram showing the reaction process](image)

**Illustration 1:** Scheme of the reaction in determining hemoglobin using the azide methemoglobin method.

The bivalent iron of the oxyhemoglobin and the desoxyhemoglobin becomes oxidized by **sodium nitrite** $\text{NaNO}_2$ to trivalent iron, in methemoglobin.

Existing and formed methemoglobin and azide ions from **sodium azide** $\text{NaN}_3$ form a colored complex which exhibits maximal absorption at 540 and 575 nm and hence it can be quantitatively determined photometrically.

2.4.2. Principle of photometric measurement

In the HemoPoint® H2 photometer the extinction of transmitted light is determined as follows:

![Diagram showing the photometric measurement principle](image)

**Illustration 2:** Principle of photometric transmitted light measurement.

$P_0$: 100 % - light intensity, $P$: remaining light intensity, $b$: distance through the solution.
For this purpose, light is directed through to a photodetector, first through no analyte: $P_0$ and then through the analyte: $P$, by means of which the transmission $T$ is measured (see equation 1). Using the extinction $A$ (amount absorbed) calculated from this (see equation 2) and using Lambert-Beers Law (see equation 3), the concentration of the hemoglobin in the cuvette can be determined.

\[ T = \frac{P}{P_0} \quad (1) \]

\[ A = \log \frac{P}{P_0} \quad (2) \]

Equation 1: Calculation of transmission $T$

Equation 2: Calculation of extinction (amount Absorbed) $A$

\[ \text{Equation 3: Lambert-Beers Law} \]
\[ a \quad \ldots \text{Proportionality constant} \]
\[ b \quad \ldots \text{Distance through the solution in the cuvette} \]
\[ c \quad \ldots \text{Concentration of the solution} \]

If the concentration is expressed in mol per litre, the proportionality constant ‘$a$’ becomes the molar extinction coefficient $\varepsilon$:

\[ A = abc \quad (3) \]

Equation 3: Lambert-Beers Law

Equation 4: Lambert-Beers Law with molar extinction coefficient $\varepsilon$

The set of equations (2 and 4) can now be solved for the concentration $c$:

\[ c = K \log \frac{P_0}{P} \quad (5) \]

with

\[ K = \frac{k}{b \varepsilon} \quad (6) \]

Equation 5: Calculation of the concentration $c$

Equation 6: Multiplier $K$ expressed as a function of $k$, $b$, $\varepsilon$

Where $k$ is proportionality factor for measurement method correction (taking into account source and detector characteristics, as well as constructional conditions).
2.4.3. Determining the hemoglobin concentration

Illustration 3: Typical absorption spectrum of an azide methemoglobin solution shown with two LED emission spectra

Illustration 3 shows a typical spectrum of azide methemoglobin as derived from the reaction with whole blood. In the HemoPoint® H2, the spectra is measured at two measuring regions: the first region lies in the wavelength range 560 - 575 nm and interrogates a region of the spectra that changes strongly with concentration (high absorption). A second region lies in the infrared zone of 850 - 900 nm, which changes very weakly with concentration (low absorption). LED (light emitting diode) emission spectra in the two regions are also identified above.

Dual wavelength measurement
While the signal measured in the 560 to 575 nm range provides primary information about the amount of hemoglobin, it is also helpful for improvements in accuracy to utilize a second wavelength where hemoglobin levels do not greatly affect the signal, as is demonstrated in the infrared zone of 850 - 900 nm. This second wavelength allows correction for the optical properties of the cuvette, including reflective losses and turbidity of the sample.

Use of LED’s for light sources
Because of the fact that only a small section of the spectrum is of interest, LED’s as light sources and a photodiode as a detector are utilized. The LED’s are selected so that the central wavelengths lie in the measuring windows: 570 nm and 880 nm. These are operated sequentially during the measurement process. A photodiode is utilized to generate a measurable current from the illumination passing through the cuvette.
Using two wavelengths, Equation 5 can now be modified in the following manner:

\[
\begin{align*}
 c &= K \left( \log \frac{P_{570}}{P_{880}} - \log \frac{P_{570}^D}{P_{880}^D} \right) \\
 &= K \left( \log \frac{P_{570}}{P_{880}} - \log \frac{P_{570}^D}{P_{880}^D} \right)
\end{align*}
\]  

(7)

**Equation 7:** Calculation of the concentration by using two wavelengths of light, 570nm and 880nm

Note that subtraction of the two wavelength in the logarithmic domain corresponds to division (ratio) in the linear range.

with

\[
K = \frac{k}{b \varepsilon}
\]

(6)

**Equation 6:** Multiplier \( K \) expressed as a function of \( k, b, \varepsilon \)

The photodiode used as a detector in the HemoPoint® H2 delivers a current which is linear and proportional to the intensity of light passing through the sample. However, small signal currents may be present in the absence of light signals due to thermal and amplifier effects.

In order to take the dark signal (and other signals) into account, the following measurements are recorded in the measurement sequence:

1. with the cuvette holder open (measuring a "blank" i.e. 100% T light path, no cuvette)
   a) determination of the dark current \( I_{D_{\text{open}}} \)
   b) determination of the currents for 100% transmission and \( I_{0_{570nm}} \) and \( I_{0_{880nm}} \)

2. with the cuvette holder closed (measuring a sample in a cuvette)
   a) determination of the dark current \( I_{D_{\text{closed}}} \)
   b) determination of the currents with transmission reduced by absorption \( I_{570nm} \) and \( I_{880nm} \)

Determining the dark currents \( I_{D_{\text{open}}} \) and \( I_{D_{\text{closed}}} \), helps to compensate for electrical offset and increase the measurement accuracy. Determining the 100% transmission currents, \( I_{0_{570nm}} \) and \( I_{0_{880nm}} \) is used for calculation and also helps to alert the system to any changes in light output.

The 100% and dark measurements can now be inserted into equation 7 as follows:

\[
c = K \cdot \left( \frac{I_{0_{570}} - I_{D_{\text{open}}}}{I_{570} - I_{D_{\text{closed}}}} \right) \cdot \left( \frac{I_{0_{880}} - I_{D_{\text{open}}}}{I_{880} - I_{D_{\text{closed}}}} \right)
\]

(8)

**Equation 8:** Calculation of the concentration with the light and dark measurements determined
2.4.4. Calibration

The proportionality factor K is determined empirically for each instrument by calibration against the cyanmethemoglobin methods\(^4\),\(^5\),\(^6\) and is retained in the instrument as a calibration parameter.

No calibrator for Hb determination exists which can be reduced to SI units. For calibrating the reference process however, there is an internationally agreed calibrator available, with cyanmethemoglobin in bovine blood hemolysate BCR-522 from EU-BCR (Bureau Communautaire des références), which has a substance concentration of \(49.61 \pm 0.08 \mu \text{mol/l}\), related to the monomer\(^8\).

Calibration of the instrument can be periodically verified by optical and reagent standards. Stanbio Laboratory recommends daily use of the accessory optical control cuvette to verify the instrument is operating properly (see also point 6.3 of this document).
3. Hardware description

Illustration 4: Functional block diagram of the HemoPoint® H2 Instrument

3.1. System Overview

Refer to the functional block diagram above. The HemoPoint® H2 is a microcontroller based instrument which uses a single chip microprocessor (16 bit Mitsubishi M30624 type) to perform the following general functions:

- Detect the cuvette holder state (open/closed).
- Illuminate the LED's and read and digitize the photodiode signals.
- Calculate the hemoglobin concentration based on the signals and internal calibration values.
- Communicate with the user via a graphic LCD display with touch panel- display allows review of measurement history and selection of desired options such as units.
- Communicate with an optional printer to output reported values.
- Sense mains or battery operation and illuminate the display if mains are connected.
3.2. Signal Measurement

The receiver photodiode generates a photo-current proportional to the incident light intensity as modified by the sample. This current is converted, amplified and supplied to an analog to digital converter (ADC). The digitized values from a measurement sequence (including 100%, cuvette, and dark signals) are processed by the internal microcontroller software to calculate Hemoglobin concentration.

**Illustration 5**: Block circuit diagram of the electronic measuring chain.

An ADC resolution of 14 bits is adequate to provide a hemoglobin measurement resolution of 0.1 g/dl (1 g/l) over the concentration range while taking into account ADC quantization errors.

3.3. Measuring Sequence

As described in section 2.4.3 the following measurements are made in sequence:

The first measurement series (100%) is performed in the open cuvette holder position. A repetition measurement is carried out every minute to compensate for possible temperature drift:

a) Measuring dark current \( I_{D_{\text{open}}} \)

b) Measuring zero current values \( I_{0_{570nm}} \) and \( I_{0_{880nm}} \)

The second measurement series (sample) is performed in the closed cuvette holder position:

c) Measuring dark current \( I_{D_{\text{closed}}} \)

d) Measuring currents \( I_{570nm} \) and \( I_{880nm} \)
Each measurement is averaged from 3 samples.

- The sample is measured cyclically and evaluated to determine when the reaction in the cuvette has stabilized; this is typically in the range of 1 to 3 minutes.
- A fault is generated if the measurement is out of the time or measurement window.
- The concentration is calculated using equation 8 (see page 6 of this document):
- The concentration is displayed (and if printer is used and selected, printed)

3.4. HemoPoint® H2 Optical Measurement Assembly with Cuvette holder

The HemoPoint® H2 Optical Measurement Assembly is a precision machined assembly which contains the following elements:

- Removable plastic cuvette holder (tray) which can be disinfected.
- Proximity switches to sense the open and closed conditions of the holder.
- Optical sample assembly which holds the LED's and Photodiode.
- Spring damping mechanism to gradually close the holder – this feature limits sudden movement of the cuvette and provides the following benefits:
  - Single finger touch operation to open and close the cuvette.
  - Helps keep the blood fluid in the cuvette and improves sample quality
  - Reduces contamination of the tray by limiting spills.

3.5. HemoPoint® H2 Power Supply and Battery

The HemoPoint® H2 system can be operated on battery or mains power. Refer to the block diagram on page 8 -the system has the following features:

- External 6 Volt Power Supply – this supply is rated for medical laboratory applications. The 6 volt power supply is a universal type and operates over the range of 100 – 250VAC 50/60Hz. A power supply data sheet is provided in Exhibit 4.4.
- 2 Ni-HM (Nickel Metal Hydride) rechargeable internal batteries.
- Microcontroller control of the optimum charging of the battery.
- Communication with the microcontroller regarding battery status.
- Communication with the microcontroller regarding the connection of mains power.
  - Connection to mains power enables the LCD backlight.
  - Battery only operation disables the LCD for power savings.

3.6. HemoPoint® H2 Enclosure

The HemoPoint® H2 enclosure is constructed from a molded plastic chassis in two halves -base and panel. The base holds the cuvette holder and the controller circuit board as well as external connections to the printer and power supply. The panel hold the LCD touch screen display. The enclosure is rated for laboratory use and fluid ingress resistance. Overall dimensions of the enclosure and microcuvette are attached as Exhibit 4.2. Photographs of the enclosure are provided in Exhibit 4.6.
3.7. Optional Printer

The HemoPoint® H2 system can be provided with an optional printer to print test results. The specified printer is the Seiko DPU-414 printer, which is a small footprint 40 column unit. This printer meets the requirements of the EMC and Low Voltage Directive (safety)- refer to Section 9 of this submission for compliance information. A serial interface cable connects the HemoPoint® H2 Instrument to the printer. A photograph of the printer is provided in Exhibit 4.6. A specification sheet is provided in Exhibit 4.4. (Note: the wireless printing option of the specification sheet is not utilized by Stanbio Laboratory).

4. System Software

The Stanbio Laboratory HemoPoint® H2 instrument is software controlled by means of an embedded computer, and utilizes C language software in the Mitsubishi M30624 microcontroller development environment. Refer to Section 8, Software Validation Information, for a detailed description of the device software architecture, sequence of operation, development tools, and the associated validation activities.

5. User Interface and Control Features

The Stanbio Laboratory HemoPoint® H2 user interface is provided via the LCD touch screen with "soft-menu" keys that change function depending upon the state of the instrument. Additionally, audible tones (via internal speaker) are provided for some functions such as key strikes and measurement complete.

5.1. Basic Status Screen

After a start up screen, the following screen is displayed which provides basic status.

- The "Open" mode indicates the device is ready to open for a sample.
- The "Memory" key allows review of previously measured samples.
- The "Menu" key allows access to other options (see below).
- Time and Battery status are provided to the user for convenience.
5.2. Ready Screen

Opening the cuvette holder initiates the “Ready” mode, which indicates the instrument is ready for a sample cuvette.

For basic measurements (no patient type or limits set), it is only necessary to place a sample, and close the holder. The measurement will be made and reported automatically.

The user may also select the “Patient Type” key. See Figure below for further description.

Illustration 7: Ready Screen of HemoPoint® LCD touch screen

5.3. Evaluation Screen

The “Evaluation” screen is displayed during measurement. The bar below the text fills with black over the elapsed measurement time.

Illustration 9: Evaluation Screen

During evaluation time the “Memory” and “Menu” keys are inactive and displayed faint to inform the user.
5.4. Result Screen

The "Result" screen is displayed after a measurement is complete. The standard result screen is shown below.

Illustration 10: Standard Result Screen

The user may optionally select additional information to be displayed, including results by patient type and optional estimate of Hematocrit. This has the following conditions:

- Hematocrit is estimated only for the normal Hemoglobin range (12.0 to 18.0 g/dl) and is otherwise not reported. The instrument does not estimate abnormal Hematocrit values.

- The "Patient Type" key must be selected at the "Ready" screen in order to provide patient specific information. (Refer to 5.2 for more information).

Illustration 11: Optional Result Screen with patient type and estimated Hematocrit displayed.

In the screen above "(F+)" denotes female patient type with the "( +)" + denoting Hemoglobin level above the user set screening value. This feature is useful for clinics that perform screening functions such as donor clinics.

Estimated Hematocrit is displayed as "Hct (value)(E)" where E denotes estimate.
5.5. Menu Screen

The “Menu” screen is entered from the “Basic Status” screen (refer to 5.1 above). The menu items are selected by the touch screen navigation keys as shown below.

Selecting a specific menu item by the “Up Arrow” or “Down Arrow” keys is simple. Key clicks sound for each key strike. Pressing the “OK” key accepts the selection and displays the selected submenu. Submenu’s also utilize the same key format (UP- DOWN - OK - ESC) so the user is quickly familiar with submenu choices.

5.6. Menu Functions

The menu functions are summarized below. Further detail on each menu item is available in Section 8, Software Validation Information.

<table>
<thead>
<tr>
<th>Menu Function</th>
<th>Contents and Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Info</td>
<td>Battery Status and Life statistics of the instrument</td>
</tr>
<tr>
<td>Date</td>
<td>Set Calendar Date of Instrument</td>
</tr>
<tr>
<td>Time</td>
<td>Set Time of Instrument</td>
</tr>
<tr>
<td>Unit</td>
<td>Set the Hemoglobin units reported to mmol/l; g/dl; or g/l</td>
</tr>
<tr>
<td>Hgb Limits</td>
<td>Enable or disable using of high/low limits; set limits for each patient type</td>
</tr>
<tr>
<td>Contrast</td>
<td>Set the contrast of the LCD display for best viewing</td>
</tr>
<tr>
<td>Settings</td>
<td>Language – select English, German, or Spanish</td>
</tr>
<tr>
<td></td>
<td>Date format – adjust to DD.MM.YY; MM/DD/YY; DD/MM/YY; YY-MM-DD</td>
</tr>
<tr>
<td></td>
<td>Time format – adjust the format to 12 or 24 hour format</td>
</tr>
<tr>
<td></td>
<td>Mains Frequency – set to 50 or 60Hz (internal filter function)</td>
</tr>
</tbody>
</table>
Menu functions continued:

<table>
<thead>
<tr>
<th>Menu Function</th>
<th>Contents and Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Options</td>
<td>Hematocrit Estimate – On/Off</td>
</tr>
<tr>
<td></td>
<td>Print mode – select Standard or Expanded (feeds paper between results)</td>
</tr>
<tr>
<td></td>
<td>Sound – enable / or disable the audible sound</td>
</tr>
<tr>
<td></td>
<td>Standby – set the time interval for system standby when not used</td>
</tr>
<tr>
<td></td>
<td>History – print information on 100% T, Battery, Errors, Calibration</td>
</tr>
<tr>
<td></td>
<td>Service (requires password) – Service interrogation functions</td>
</tr>
<tr>
<td>Contact</td>
<td>Contact – Company contact information</td>
</tr>
</tbody>
</table>

6.1. Functions and Attributes of the Hemo_Control Microcuvette

![Illustration 13: Hemo_Control Microcuvette](image)

The microcuvette is a precision molded plastic component which incorporates the following functions:

- Utilizes 10 μl of blood pulled by capillary action into the microcuvette.
- Holds the dry reagent chemistry (see 2.4 above) which dissolves the red blood cell walls and converts the hemoglobin to a measurable azide methemoglobin.
- Defines a short path length (0.13 mm) optical sample cell which can be measured directly by the instrument.

The operating principles, chemistry, and usable dimensions of the HemoPoint® H2 microcuvette are functionally identical to the microcuvette manufactured by HemoCue for B-Hemoglobin measurement (see section 5 of this submission for comparative information). In addition, the microcuvette has the following attributes:

- The microcuvette is suitable to be inserted into the microcuvette holder of the HemoCue and other compatible instruments. Approx. outside measurements: 35 mm long, 1.0-2.4 mm broad (adapted about the length) and 2 mm thick.
The microcuvette has a "wing" as a mechanical characteristic to ensure proper insertion into the microcuvette holder of the instrument.

Additional specifications of the microcuvette are provide in Exhibit 4.1, system specification. Dimensional drawings and photographs and of the microcuvette are provided in Exhibits 4.2 and 4.6 respectively.

6.2. Microcuvette Storage Container

The microcuvette storage container is an important component with the following features:

- Holds up to 50 microcuvettes (50 is the standard quantity).
- Ensures the storage quality of the microcuvettes by containing an integral desiccant in the lid – shelf life unopened is 14 months.
- Provides a moisture resistant seal to ambient conditions after first opening of the container – shelf life is three months after opening (Note: the user is requested by the labelling to identify to date of first opening).

A photograph of the microcuvette storage container and lid is provided in Exhibit 4.6.

6.3. Accessory Control Cuvette

Each HemoPoint® H2 System is shipped with a serialized control cuvette. This is a stable optical reference which is associated with a fixed Hemoglobin value. The control cuvette can be measured in the same manner as any sample. Comparison of the instrument reading to the control value provides clinical users a reference point for quality control.

7. Further Descriptive Information

The following information is attached to this document in the form of Exhibits.

7.1. System Specification

A System Specification is attached in Exhibit 4.1. This is a subset of the Functional Requirements Specification, which is attached in Section 8.

7.2. Overall Dimensions

Overall dimensions of the enclosure and microcuvette are attached in Exhibit 4.2. The HemoCue Microcuvette dimensions are also shown for reference.

7.3. Schematic Diagrams

The HemoPoint® H2 electronics is integrated into a single control circuit board. Schematics are attached (company confidential) in Exhibit 4.3, and are divided into the following elements: Microprocessor, Analog, Power, and Interface.
7.4. Mains Power Supply

A specification for the 6 Volt Mains power supply is attached in Exhibit 4.4.

7.5. Printer

A specification for the optional Seiko DPU-414 printer is attached in Exhibit 4.5. (Note: the HemoPoint® H2 system provides a serial cable for communication and does not utilize the wireless feature of the printer described in the data sheet).

7.6. System Photographs

System photographs are attached in Exhibit 4.6. These include the following:

- HemoPoint® H2 instrument front view
- HemoPoint® H2 instrument rear view
- HemoPoint® H2 instrument with optional Seiko printer.
- HemoPoint® H2 Microcuvette
- Microcuvette Storage Container with desiccant cover.
Section Four - Device Description

Exhibit 4.1

System Specification

Stanbio HemoPoint® H2 Hemoglobin Measurement System
1. System Performance Specifications
Section Four - Device Description

Exhibit 4.2

Overall Dimensions

Stanbio HemoPoint® H2 Instrument dimensions
Stanbio HemoPoint® H2 Microcuvette dimensions
Stanbio HemoPoint® H2 Microcuvette 3D rendering
Hemocue Microcuvette (for reference)
Section Four - Device Description

Exhibit 4.3

Schematic Diagrams

Stanbio HemoPoint® H2 Hemoglobin Measurement System
Control Circuit Board

Microprocessor Section

Analog Section

Power Section

Interface Section
Section Four - Device Description

Exhibit 4.4

Specifications

6V DC Mains Power Supply

(Dual language German – English specification sheet)
Section Four - Device Description

Exhibit 4.5

Seiko DPU-414 Printer Data Sheet
DPU Series

DPU-414 DESKTOP OR PORTABLE PRINTER

Now with Remote RF Communications
For a compact desktop or portable thermal printer, the DPU-414 is an excellent selection. It incorporates our STP printer mechanism to ensure silent and high-quality printing of characters plus high-density graphics. And in quadruple-density bit image mode, 640-dot (max.) CRT display hardcopy is possible (with horizontal vs. vertical ratio of 1:1).

- CRT display hardcopy, HEX dump copy
- Optional RF wireless transceiver
- Dual-power supply
- Support for Centronics and serial data input
- Built-in data buffer (approx. 28kb)
- 40 columns in standard characters or 80 columns in condensed characters

Wireless Printing Versatility
The DPU-414 portable thermal printer can be outfitted to handle wireless communications. For maximum flexibility and mobility, an optional RF transceiver can be connected via the printer's RS-232C port to transmit information over distances and through most structures for complete freedom. It's one more reason the DPU-414 is an excellent choice for performance and versatility.

Note: Wireless Option is not used with the EKF

Hemo_Control Hemoglobin measurement system

<table>
<thead>
<tr>
<th>Model</th>
<th>DPU414-20B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printing</td>
<td>Thermal serial hardcopy</td>
</tr>
<tr>
<td>No. of dots/line</td>
<td>320</td>
</tr>
<tr>
<td>No. of characters/line</td>
<td>40 (normal), 80 (condensed)</td>
</tr>
<tr>
<td>Character matrix</td>
<td>9 x 1 dot matrix (normal)</td>
</tr>
<tr>
<td>Width (mm)</td>
<td>90</td>
</tr>
<tr>
<td>Resolution</td>
<td>3.57 x 3.57 dots/mm, 7.14 x 3.57 dots/mm</td>
</tr>
<tr>
<td>Speed (ipm)</td>
<td>1.3, normal; 1.0, condensed</td>
</tr>
<tr>
<td>Speed (cpi)</td>
<td>527, normal; 90, condensed</td>
</tr>
<tr>
<td>Data input method</td>
<td>Serial: RS-232C, S-220, S-226</td>
</tr>
<tr>
<td>Parallel</td>
<td>8-bit parallel (Centronics) 36-pin</td>
</tr>
<tr>
<td>Dimensions (W x H x D) cm</td>
<td>26 x 17.5 x 69.5</td>
</tr>
<tr>
<td>Weight (g)</td>
<td>Approx. 580 (excluding battery)</td>
</tr>
<tr>
<td>Power supply</td>
<td>Optional 6.5 VDC @ 2.0 A, 9VDC AC adapter</td>
</tr>
<tr>
<td>Service life</td>
<td>Pulse activation 500,000 lines</td>
</tr>
<tr>
<td>Absorption resistance</td>
<td>1 x 10⁻⁶ ± 5% max</td>
</tr>
<tr>
<td>Paper</td>
<td>Width (mm) 112, Vertical</td>
</tr>
<tr>
<td>Cut method</td>
<td>Tear bar</td>
</tr>
<tr>
<td>Operating temperature °C</td>
<td>0 to 40</td>
</tr>
<tr>
<td>Storage environment °C</td>
<td>20 to 60</td>
</tr>
<tr>
<td>Input buffer size</td>
<td>25 kbytes</td>
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<tr>
<td>Accessories</td>
<td>Power supply: Part 4 PW-007-U1, 6.5 VDC AC adapter, 9VDC AC adapter</td>
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<tr>
<td>RF Communications</td>
<td>Part 4 BP-1000, 6.5 VDC AC adapter</td>
</tr>
<tr>
<td>Outdoor range</td>
<td>500-1500 ft (normal construction)</td>
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<tr>
<td>Connectivty</td>
<td>2 mi. line of sight ( Omni-directional antenna)</td>
</tr>
<tr>
<td>Frequency band</td>
<td>2.4 GHz license free</td>
</tr>
<tr>
<td>Radio data rate</td>
<td>0.6 Mbps full duplex</td>
</tr>
<tr>
<td>Security</td>
<td>Rapid/fixed frequency hopping, Data encryption software support</td>
</tr>
<tr>
<td>Antennas</td>
<td>Omni-directional (up to 5 dB)</td>
</tr>
</tbody>
</table>

Application examples
- Portable/mobile/wireless computing,
- Instrumentation, analyzers, point of sale, gaming

Seiko Instruments Inc.

Seiko Instruments USA Inc.
Micro Printer Division
2900 West Lomita Blvd., Torrance, CA 90506
Phone: (800) 553-8570 • Facsimile: (310) 517-6154
E-Mail: sumpci.sd@seikosupport.com
World Wide Web: http://www.seikoprinters.com

Specifications subject to change without notice.

Records processed under FOIA Request 2014-5238; Released 10/16/14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s)  

Subject: 510(k) Number

To: The Record - It is my recommendation that the subject 510(k) Notification:

☐ Refused to accept.
☐ Requires additional information (other than refuse to accept).
☒ Is substantially equivalent to marketed devices.  21 CFR §641.5620 Automated HemoCue System
☐ NOT substantially equivalent to marketed devices.
☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?  ☐ YES ☑ NO
Is this device subject to the Tracking Regulation?  ☐ YES ☑ NO
Was clinical data necessary to support the review of this 510(k)?  ☒ YES ☐ NO
Is this a prescription device?  ☒ YES ☐ NO
Was this 510(k) reviewed by a Third Party?  ☐ YES ☑ NO
Special 510(k)?  ☐ YES ☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  ☐ YES ☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
☒ A 510(k) summary OR ☐ A 510(k) statement
☐ The required certification and summary for class III devices
☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) 

Animal Tissue Source  ☐ YES ☑ NO  Material of Biological Origin  ☑ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
☐ No Confidentiality ☐ Confidentiality for 90 days  ☑ Continued Confidentiality exceeding 90 days

Predicate Product Code with class:  Additional Product Code(s) with panel (optional):

Review:  
(Branch Chief) (Branch Code) (Date)

Final Review:  
(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Revised: 4/2/03
510(k) "SUBSTANTIAL EQUIVALENCE"
DECISION-MAKING PROCESS

1. Does New Device Have Same
   Indication Statement? NO

2. Does New Device Have Same
   Use and May be "Substantially Equivalent"? NO

3. New Device Has Same
   Intended Use and May be “Substantially Equivalent”

4. Do the Differences Alter the Intended
   Therapeutic/Diagnostic, etc. Effect
   (in Deciding, May Consider Impact on
   Safety and Effectiveness)?** Y

5. New Device Has New Intended Use

6. Could the New
   Characteristics Affect Safety or
   Effectiveness? NO

7. Are the Descriptive
   Characteristics Precise Enough
   to Ensure Equivalence? NO

8. Are Performance Data
   Available to Assess Equivalence? YES

   YES
   Performance Data Required

   NO
   Performance Data Demonstrate
   Equivalence?

   NO
   To A

   YES
   “Substantially Equivalent”
   Determination

9. Do Accepted Scientific
   Methods Exist for
   Assessing Effects of
   the New Characteristics? NO

10. Are Performance Data Available
    To Assess Effects of New
    Characteristics?*** NO

11. Performance Data Demonstrate
    Equivalence?

   YES
   To A

   NO

* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.
"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K032482

Reviewer: Larry J. Brindza
Division/Branch: OIVD/ Division of Immunology and Hematology Devices
Device Name: HemoPoint® H2 Hemoglobin Measurement System and HemoPoint® H2 Cuvettes
Product To Which Compared (510(K) Number If Known): HemoCue B-Hemoglobin System with microcuvette (K961312) and HemoCue Photometer (K832020)

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is Product A Device</td>
<td>X</td>
</tr>
<tr>
<td>2. Is Device Subject To 510(k)?</td>
<td>X</td>
</tr>
<tr>
<td>3. Same Indication Statement?</td>
<td>X</td>
</tr>
<tr>
<td>4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?</td>
<td></td>
</tr>
<tr>
<td>5. Same Technological Characteristics?</td>
<td>X</td>
</tr>
<tr>
<td>6. Could The New Characteristics Affect Safety Or Effectiveness?</td>
<td></td>
</tr>
<tr>
<td>7. Descriptive Characteristics Precise Enough?</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>8. New Types Of Safety Or Effectiveness Questions?</td>
<td></td>
</tr>
<tr>
<td>9. Accepted Scientific Methods Exist?</td>
<td></td>
</tr>
<tr>
<td>10. Performance Data Available?</td>
<td>X</td>
</tr>
</tbody>
</table>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.
1. **Intended Use:** The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary whole blood of adults, infants, and children in a professional point-of-care setting. The microcuvettes part number 3010-100 are indicated for use in the Hemopoint® H2 Hemoglobin Measurement System and HemoCue® B-Hemoglobin Photometer.

2. **Device Description:** The HemoPoint H2 Hemoglobin Measurement System is comprised of a HemoPoint H2 Hemoglobin Photometer and HemoPoint H2 disposable Cuvettes. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste. The HemoPoint H2 System is identical to the predicate device in intended use, sample requirements, and methodology. The HemoPoint H2 system is different than the predicate in that data handling is different. The HemoPoint H2 system has time/data logging and data storage capability. The predicate device has these capabilities only with the optional data management module.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

7. **Explain how descriptive characteristics are not precise enough:**

   Performance characteristics data are necessary to demonstrate effectiveness.

11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**

   Accuracy, precision, stability, interference, and expected values performance data demonstrate the substantial equivalence of the device. In addition, a hazard analysis and software documentation have been provided.
**Internal Administrative Form**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the firm request expedited review?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Did we grant expedited review?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Have you verified that the Document is labeled Class III for GMP purposes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. If, not, has POS been notified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Is the product a device?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Is the device exempt from 510(k) by regulation or policy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Is the device subject to review by CDRH?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Are you aware that this device has been the subject of a previous NSE decision?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Are you aware of the submitter being the subject of an integrity investigation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. If, yes, consult the ODE Integrity Officer.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
   K032482
B. Analyte:
   Hemoglobin
C. Type of Test:
   Quantitative, photometric measurement of hemoglobin
D. Applicant:
   Stanbio Laboratory
E. Proprietary and Established Names:
   HemoPoint® H2 Hemoglobin Measurement System and HemoPoint® H2 Cuvettes
F. Regulatory Information:
   1. Regulation section:
      21 CFR 864.5620, Automated hemoglobin system
   2. Classification:
      Class II
   3. Product Code:
      GKR
   4. Panel:
      Hematology (81)
G. Intended Use:
   1. Indication(s) for use:
      The HemoPoint H2 Hemoglobin Measurement System is intended for the
      quantitative determination of hemoglobin in arterial, venous, or capillary
      whole blood of adults, infants, and children in a professional point-of-care
      setting. The microcuvettes part number 3010-100 are indicated for use in the
      HemoPoint® H2 Hemoglobin Measurement System and HemoCue® B-
      Hemoglobin Photometer.
   2. Special condition for use statement(s):
      The microcuvettes are intended to be used only once and must be disposed of
      after use as potentially infectious waste.
   3. Special instrument Requirements:
      N/A
H. Device Description:
   The HemoPoint H2 Hemoglobin Measurement System is comprised of a HemoPoint
   H2 Hemoglobin Photometer and HemoPoint H2 disposable Cuvettes.
I. Substantial Equivalence Information:
   1. Predicate device name(s):
      HemoCue B-Hemoglobin System with microcuvette (K961312)
      HemoCue Photometer (K832020)
2. **Predicate K number(s):**
   See above section.

3. **Comparison with predicate:**

<table>
<thead>
<tr>
<th>Similarities</th>
<th>Item</th>
<th>Device</th>
<th>Predicate 1</th>
<th>Predicate 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>Quantitative determination of hemoglobin</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>Sample Requirements</td>
<td>Venous, arterial, or capillary blood</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>Methodology</td>
<td>Modified azide methemoglobin Hct=estimation from hemoglobin</td>
<td>Hgb=Same</td>
<td>Hgb=Same</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hct= None</td>
<td>Hct= None</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Differences</th>
<th>Item</th>
<th>Device</th>
<th>Predicate 1</th>
<th>Predicate 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Handling</td>
<td>Time/Data logging and data storage capability</td>
<td>Only with data management module</td>
<td>Only with data management module</td>
<td></td>
</tr>
</tbody>
</table>

J. **Standard/Guidance Document Referenced (if applicable):**
3. *H11-A3 Procedures for the Collection of Arterial Blood Specimens; Approved Standard, NCCLS.*
6. *EP5-A Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline, NCCLS.*

K. **Test Principle:**
The device uses a modified azide methemoglobin method (Vanzetti) to measure hemoglobin.

A small amount of blood is loaded into the microcuvette via capillary action. The cuvette is then inserted into the HemoPoint H2 photometer where the color produced by the chemical reaction in the cuvette is measured. Results are displayed by LED readout.
L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

<table>
<thead>
<tr>
<th></th>
<th>Hemo Point H2 Cuvette In HemoPoint Device</th>
<th>HemoPoint H2 Cuvette In HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With-in Run (CV)</td>
<td>Total (CV)</td>
</tr>
<tr>
<td>Hemoglobin/Low (10.7 g/dL)</td>
<td>0.9%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Hemoglobin/Normal (12.9 g/dL)</td>
<td>0.7%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Hemoglobin/High (17.3 g/dL)</td>
<td>0.6%</td>
<td>1.2%</td>
</tr>
</tbody>
</table>

   b. Linearity/assay reportable range:
      0-25.6 g/dL
   c. Traceability (controls, calibrators, or method):
      Device calibrated against NCCLS reference method
   d. Detection limit:
      N/A
   e. Analytical specificity:
      N/A
   f. Assay cut-off:
      N/A

2. Comparison studies:
   a. Method comparison with predicate device:
      Comparison to NCCLS H15-A3 (y=0.023+1.006x, R=0.999, N=174 [duplicate measurements])

      Comparison to predicate HemoCue (y=0.233+1.001x, R=0.998, N=286 [duplicate measurements])

      Comparison of HemoPoint H2 cuvettes in Hemocue predicate (y=0.139+0.986x, R=0.999, N=286 [duplicate measurements])

   b. Matrix comparison:

      Capillary Samples, 4 sites (y=0.946x+0.3742x, R²=0.8256, N=275)
      Venous Samples, 4 sites (y=1.0005x-0.2334x, R²=0.9962, N=286)
      Arterial samples, 1 site (y=0.9868x-0.285, R²=0.997x, N=10)

3. Clinical studies:
   a. Clinical sensitivity:
      N/A
b. Clinical specificity:
   N/A

c. Other clinical supportive data (when a and b are not applicable):
   N/A

4. Clinical cut-off:

5. Expected values/Reference range:
   Expected values were based on the medical literature:

   Women: 12.0-16.0 g/dL
   Men: 13.0-17.5 g/dL
   Children, depending on age: 9.0-24 g/dL

M. Conclusion:
   Stanbio Laboratory has demonstrated that the HemoPoint H2 Hemoglobin Measurement System is substantially equivalent to the HemoCue B-Hemoglobin System.
N. Other Supportive Information:
   The Indications for Use Statement originally stated that the HemoPoint H2 microcuvettes are indicated for use in the HemoPoint H2 Hemoglobin Measurement System “and compatible measurement systems.” This last term was changed to “and the HemoCue measurement system.” See my telephone memo dated 10-8-03.

O. Administrative Information:

1. Applicant contact information:
   a. Name of applicant:
      Stanbio Laboratory
   b. Mailing address:
      1261 North Main Street, Boerne, Texas 78006
   c. Phone #:
      830-249-0772
   d. Fax #:
      830-249-0851
   e. E-mail address (optional):
      kjohnson@stanbio.com
   f. Contact:
      Kirk Johnson, QA/Regulatory Affairs Manager

2. Review documentation:
   See phone memo dated 10-8-03

P. Reviewer Name and Signature:

[Signature]
Larry J. Brindza
CDRH/OIVD/DIHD
Indications page-a
updated doc...

Section 2 update S
and E state...

Dear Mr. Brendza:

Thank you for discussing Stanbio's options regarding our recent 510(k) submission for the HemoPoint H2 system.

Attached please find the 2 Word documents covering the "Indications for Use Statement" and the "Safety and Effectiveness Statement" as per our telephone conversation.

I trust this will satisfy your requirements to move our submission along in the 510(k) process.

If I can be of any further assistance, please do not hesitate to contact me.

Please acknowledge the receipt of this e-mail.

Sincerely,

Alberto E. Blanco
Vice President Marketing
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006 USA
Tel: 830.249.0772 x-106 Fax: 830.249.0851
e-mail: ablanco@stanbio.com www.stanbio.com

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Stanbio Laboratory Boerne, TX 78006
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510(k) Number (if known): K032482

Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications for use:

The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

Trade Name: HemoPoint® H2 Hemoglobin Measurement System
Common/Classification Name: Automated Hemoglobin System
Device Classification: Class: II
CFR: 21 CFR 864.5620
Product Code: GKR
Manufacturer: Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint®
H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

The recognized reference method for tHb determination (tHb = total hemoglobin) is the
cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood
sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed
and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium
hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with
cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable,
colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm.
This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN₃ and thus was able to reduce the toxicity of
the reagent mixture considerably.

Vanzetti’s method is also known as the azide methemoglobin method. A modified azide
methemoglobin method is used in the HemoPoint® H2 system.

In the HemoPoint® H2, however, the use of microcuvettes with short light pathways makes it
possible to analyze undiluted blood. The filled cuvette is inserted into the HemoPoint® H2
photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb
level is calculated and displayed.

In the HemoPoint® H2 photometer the light transmitted through the cuvette sample is
measured.

Principle of photometric transmitted light measurement.

\[ P_0: 100\% \text{ - light intensity, } P: \text{remaining light intensity, } b: \text{distance through the solution} \]

For this purpose, light is directed through the blood sample and the transmission T is
measured. From the amount of light absorbed by the sample, the concentration of the
hemoglobin in the cuvette can be calculated using Lambert-Beers Law.

Light emitting diodes (LED’s) are used as light sources and a photodiode to detect the light.
The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm
(for turbidity compensation).
Section Two – Statements/Certifications

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Intended Use:
The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/L or 12.0 to 18.0 g/dL). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values and will not be reported.

For In Vitro Diagnostic Use Only

Comparison To Predicate Device:

Precision:
Within-run imprecision HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue Device ≤ 2%

<table>
<thead>
<tr>
<th>Hemoglobin/high (17.3 g/dL)</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EP5-A):</td>
<td>Sw 0.111 g/dL, CV 0.6 %</td>
<td>Sw 0.103 g/dL, CV 0.6 %</td>
</tr>
<tr>
<td>Total Precision (NCCLS EP5-A):</td>
<td>S 0.207 g/dL, CV 1.2 %</td>
<td>S 0.162 g/dL, CV 0.9 %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin/low (10.7 g/dL)</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EP5-A):</td>
<td>Sw 0.095 g/dL, CV 0.9 %</td>
<td>Sw 0.068 g/dL, CV 0.6 %</td>
</tr>
<tr>
<td>Total Precision (NCCLS EP5-A):</td>
<td>S 0.114 g/dL, CV 1.1 %</td>
<td>S 0.086 g/dL, CV 0.8 %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin/normal (12.9 g/dL)</th>
<th>HemoPoint® H2 cuvette measured in HemoPoint® H2 device</th>
<th>HemoPoint® H2 measured in HemoCue device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Precision (NCCLS EP5-A):</td>
<td>Sw 0.084 g/dL, CV 0.7 %</td>
<td>Sw 0.102 g/dL, CV 0.8 %</td>
</tr>
<tr>
<td>Total Precision (NCCLS EP5-A):</td>
<td>S 0.148 g/dL, CV 1.1 %</td>
<td>S 0.134 g/dL, CV 1.0 %</td>
</tr>
</tbody>
</table>

Between-Day Imprecision Single observation, 20 days

10.7 g/dL: SD 0.102 g/dL, CV 1.0 %
12.9 g/dL: SD 0.141 g/dL, CV 1.1 %
17.3 g/dL: SD 0.169 g/dL, CV 1.0 %

10.9 g/dL: SD 0.094 g/dL, CV 0.9 %
13.0 g/dL: SD 0.126 g/dL, CV 1.0 %
17.2 g/dL: SD 0.148 g/dL, CV 0.9 %

Correlation Study:

Correlation coefficient HemoPoint® H2 System compared to NCCLS H15-A3 reference method, venous blood: ≥ 0.98

Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to Hemocue System, venous blood: 2 – 3
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Experimental Data:

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

| Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood (Summary from 4 Clinical Study Sites) | - Y = 0.023 + 1.006X  
- R = 0.999  
- N = 174, duplicate measurements  
- Range 3.31 g/dL to 24.4 g/dL |

| Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites) | - Y = -0.233 + 1.001X  
- R = 0.998  
- N = 286, duplicate measurements  
- Range 3.25 g/dL to 23.85 g/dL |

HemoPoint® H2 cuvettes measured in HemoCue device:

| Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites) | - Y = 0.139 + 986X  
- R = 0.999  
- N = 286, duplicate measurements  
- Range 3.25 g/dL to 23.85 g/dL |

Comparison to Predicate Device:

<table>
<thead>
<tr>
<th>Specification</th>
<th>HemoPoint® H2</th>
<th>HemoCue</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument</td>
<td>No. 1</td>
<td>No. 2</td>
<td>No. 1 = No. 2</td>
</tr>
<tr>
<td>Measurement range</td>
<td>0 - 25.6 g/dL</td>
<td>0 - 25.6 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Specified range</td>
<td>0 - 25.6 g/dL</td>
<td>0 - 23.5 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Specified accuracy</td>
<td>± 0.3 g/dL at ≤ 14 g/dL</td>
<td>± 0.3 g/dL at ≤ 14 g/dL</td>
<td>equivalent</td>
</tr>
<tr>
<td>Sample material</td>
<td>venous, arterial or capillary human blood</td>
<td>venous, arterial or capillary human blood</td>
<td>equivalent</td>
</tr>
<tr>
<td>Measuring time</td>
<td>Approximately 30 - 60 sec</td>
<td>Approximately 30 - 60 sec</td>
<td>measuring time depends on the concentration</td>
</tr>
<tr>
<td>Measuring units</td>
<td>mol/L, g/dL, g/L</td>
<td>mol/L, g/dL, g/L</td>
<td>equivalent</td>
</tr>
<tr>
<td>Calibration</td>
<td>against NCCLS reference method</td>
<td>against ICSH reference method</td>
<td>NCCLS is current version of the method</td>
</tr>
<tr>
<td>Method</td>
<td>Azidemethemoglobin method (Vanzetti)</td>
<td>Azidemethemoglobin method (Vanzetti)</td>
<td>equivalent</td>
</tr>
</tbody>
</table>

Conclusion / Substantial Equivalence:
The HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes and the predicate devices, HemoCue B-Hemoglobin System with microcuvette are substantially equivalent based on design and function.

Kirk Johnson  
QA/Regulatory Affairs Manager  
Stanbio Laboratory  
2 - 4
Brindza, Larry J.

From: Kirk Johnson [Kjohnson@stanbio.com]
Sent: Wednesday, October 08, 2003 6:43 PM
To: <"Larry Brenza"
Subject: 510(k) Submission K032482

Dear Mr. Brenza,

Thank you for your earlier phone call concerning Stanbio's 510(k) submission for HemoPoint H2. I appreciate you wanting to move the approval forward and gave me the opportunity to actually email amended Indications for Use Statements to accomplish this.

Unfortunately, I cannot do this today as I have to consult with other individuals here at Stanbio. Removing the statement to exclude use of the cuvettes on other compatible instruments (specifically HemoCue) changes many of our plans for distribution. However, I do want to let you know that we will resolve this as quickly as possible so approval can be granted.

Again, I do wish to thank you for giving us the opportunity to amend the documents electronically so we would not be delayed. I believe this can be resolved quickly.

Sincerely,

Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

phone: 830 249-0772, ext. 126
Fax: 830 249-0851
e-mail: kjohnson@stanbio.com

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PHONE MEMO

Date: 10-8-03

Between: Larry J. Brindza, Scientific Reviewer, Division of Immunology and Hematology Devices, OIVD, HFZ-440

And: Kirk Johnson, QA/Regulatory Affairs Manager, Stanbio Laboratory

Subject: Stanbio Laboratory, HemoPoint® H2 Hemoglobin Measurement System and HemoPoint® H2 Cuvettes.

Phone call to Mr. Johnson. I told Mr. Johnson I had a couple of questions and comments:

1. As stated in the cover letter, does Stanbio Laboratory actually manufacture the device or is it manufactured for Stanbio? Mr. Johnson stated the device is actually manufactured by a company called EKF of Germany. I told Mr. that for the sake of accuracy in the labeling, as stated in 21 CFR 801.1, "Manufactured for _____" or "Distributed by _____" would be more accurate. Mr. Johnson said the appropriate changes would be made.

2. The Indications for Use statement and 510(k) Summary pages state the HemoPoint H2 is also indicated for "...and compatible measurement systems." I told Mr. Johnson if Stanbio cannot provide the data to support the statement, then the statement would have to be changed or removed. Mr. Johnson said he would check with his managers about the statement.

3. I pointed out to Mr. Johnson several conflicting statements in the Operator's Manual and package insert and recommended that the labeling be changed to conform to 809.10 and make sense to the user. Mr. Johnson said the changes would be made.

Mr. Johnson said he would contact me ASAP by Friday about point number 2.

10-10-03, Phone call to Stanbio Laboratory. Mr. Johnson was not in the office and so I talked to Mr. Alberto Blanco, Vice President for Marketing. I told Mr. Blanco about the conflicting Indications for Use statement and gave him four choices:

1. Provide data to support "...and compatible measurement systems;"
2. Remove the term "...and compatible measurement systems;"
3. Add the name of the HemoCue instrument in place of "...and compatible measurement systems;"
4. Not change the statement and receive a decision of NSE.

Mr. Blanco said he would have to check with the President of Stanbio. Mr. Blanco called me about two hours later and said their choice would be to add the name of the HemoCue Instrument in place of "...and compatible measurement systems." I asked Mr. Blanco to send a corrected Indications for Use Statement and the corrected page from the 510(k) Summary of Safety and Effectiveness. I told him I would proceed with finishing the documentation of the submission.