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Radiometer OSM3 Hemoximeter Calibration Verification

Background

This document provides an overview of the methods used for quality control, calibration, and calibration testing of the Radiometer OSM3 Hemoximeter. In addition this document provides a detailed procedure for verifying the optical alignment of the monochromator in the OSM3.

Calibration and Quality Control*

The Radiometer OSM3 Hemoximeter Operator's Manual provides numerous "calibration" and quality control procedures. These include the daily use of dyes to ensure that the instrument is reading "properly". While these dyes (Hemoximetry Qualicheck solutions) provide an excellent tool for performing statistical process control on your OSM3, their use does not actually "calibrate" the instrument in the sense that no adjustments are made to the OSM3 to alter the values that it obtains when it makes a measurement.

The calibration procedures in the Operator's Manual include Water Calibration and Total Hemoglobin (tHb) Calibration. Water Calibration occurs on a user-selectable schedule, settable from once every ½ hour to once every 8 hours. It can also be manually triggered by pressing the CAL button on the front panel. This "calibration" is simply a measure of the amount of light received by the photodiodes when only rinse solution is in the sample cuvette. This is a crucial measurement because it is the difference between the light levels measured (at six discrete center wavelengths) during the Water Calibration and the light levels measured on the blood sample that is used to determine the measurement parameters (the concentrations of the various species of hemoglobin and the tHb).

The tHb calibration procedure actually sets the OSM3 measurement for the tHb Calibrating Solution to 12.5 g/dL. This procedure should make the measurement of tHb on blood samples accurate to within approximately ±0.1 g/dL.

Measurement Accuracy for Hemoglobin Concentrations

The Quality Control procedures (using Hemoximetry Qualicheck solutions) do not appear to adjust the measurement accuracy of the OSM3 with respect to the measurement of the concentrations of the four species of hemoglobin (oxyhemoglobin, carboxyhemoglobin, methemoglobin, and reduced hemoglobin). Further, it appears that the measurement accuracy of these parameters is only very roughly checked by the use of the Hemoximetry Qualicheck solutions. This is evident, in part, from the wide range of acceptance levels specified for the hemoglobin concentration measurements performed on the Hemoximetry Qualicheck solutions.

The absolute accuracy of measurement of the hemoglobin parameters is dependent upon the alignment of the monochromator in the OSM3. The monochromator receives the light passed through the sample cuvette and diffracts it into a spectrum. A set of six discrete photodiodes positioned at precise locations along the output plane of the monochromator then detect narrow spectral bands of the light transmitted through the cuvette at six specific center wavelengths.

As long as the monochromator is properly aligned, the correct wavelengths of light strike each of the individual photodiodes. If, however, the monochromator shifts out of alignment, then the measurements of the four different species of hemoglobin will not be accurate. And, generally speaking, it will be progressively more inaccurate the less oxygenated the blood samples being tested.

Monochromator Alignment Testing

It is interesting to note that there does not appear to be a procedure in the Operator's Manual for testing the alignment of the monochromator in the OSM3 even though this is the heart of the instrument and the key to accurate measurements. It is possible that, in the past, when the Radiometer service personnel showed up twice a year to align the instrument there was no need for such a procedure. Now, however, with Radiometer no longer supporting these instruments, it is important that scientists and clinicians still using this instrument have a way to verify that the monochromator is properly aligned.

In brief the method for checking the alignment of the monochromator is as follows:

1. Zero out all correction factors that the user has imposed on the OSM3.
2. Set the OSM3 to measure **functional oxygen saturation (HbO_2 Sat)** in percentage.
3. Draw a sample of fresh blood from a healthy, non-smoking subject.
4. Fully oxygenate the blood sample.
5. Test the blood in the OSM3.
6. If the oxygen saturation is between 99.4% and 100.4% then Radiometer considers the system to be properly aligned. **(Note that when Kestrel Labs aligns these instruments they are aligned to considerably tighter specifications; more specifically, to an oxygen saturation reading between 99.8% and 100%.)**

Alignment Check Procedure (Detailed Description)

Caution: This procedure should only be performed if your lab has the services of a qualified phlebotomist and the proper safety procedures and policies in place for the safe handling of human blood. Read through the entire procedure to ensure that you are fully capable of and comfortable with performing this procedure and have all the necessary equipment before attempting to perform this procedure.

1. First verify that the OSM3 is set up to read Adult Human blood. If the OSM3 is set up to read fetal hemoglobin ("HbF %") or an alternate mammalian species ("Ani"), see the Operator's Manual for details on how to reset the instrument for use on Adult Human blood or contact Kestrel Labs for detailed instructions.)
2. Set all corrections to "0". (See Programs section in the Operator's Manual for further details.)
    a. With the inlet flap closed, depress and hold down the Aspirate button (or key) and then depress the Cal button until the Enter key lights up. Then release the Cal button and then the Aspirate button.
    b. Depress and hold down the Cal button (or key) and then depress the Enter button. Then release the Enter button and then the Cal button. The screen should display "corr." (Note this step will have to be repeated if the HbF % mode is enabled.)
    c. Depress the Enter key repeatedly to step through all the corrections in order: tHb corr, HbO/HbO2SAT corr, HbCO corr, and MetHb corr.

d. Verify that each of the corrections are set to zero (or no correction). The tHb screen should show 1.00, below a set of dashes, if there is no tHb correction. All other parameters should show only 100 or 0.0 values if there are no corrections set.

e. Continue all the way through the corrections program by repeatedly pressing the Enter key until the OSM3 returns to normal operating mode.

3. Set the OSM3 to Functional Saturation mode (Radiometer calls this HbO_2 SAT mode. If the display already reads HbO_2 SAT then this step can be skipped).
    a. Repeat steps 2.a. and b. above. Again repeat step 2.b. until the display shows all measurement parameters and the tHb line shows four blinking 8's in a row.
    b. Depress the Enter key once and the blinking should shift to the second line on the display with the HbO_2 annunciator blinking as well. Depress the "+" key to change the HbO_2 annunciator to read HbO_2 SAT.
    c. Press and hold the Enter key until the display returns to the normal operating mode.
4. Draw a two to five cc venous sample of fresh blood from a healthy, non-smoking subject into a heparinized syringe.
5. After properly heparinizing the blood sample, move the sample into a large syringe (30 to 60 cc) and then fill the remainder of the syringe with approximately 95% oxygen and 5% CO_2.
6. Rotate the syringe so that the blood fully coats the walls of the syringe. Continue rotating the syringe for a minimum of five minutes continuously to fully oxygenate the sample.
7. Purge the excess gas from the syringe, and then test the blood sample in the OSM3.
8. If the oxygen saturation is between 99.4% and 100.4% then Radiometer considers the system to be properly aligned. (Note that Kestrel Labs aligns the instrument for an oxygen saturation reading between 99.8% and 100%.)
9. If the saturation is outside this range the monochromator may be out of alignment and you may wish to have the instrument serviced.

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[*] Kestrel Labs in not an authorized service center for repair of the OSM3. Kestrel Labs makes no guarantees or promises whatsoever in servicing the Radiometer OSM3, in providing service parts or solutions, or as to the accuracy or effectiveness of any procedures or other documentation provided by Kestrel Labs in reference to the Radiometer OSM3. The owner and/or end user assume all responsibilities and risks associated with the use of these procedures or documentation, any repair or service performed on the Radiometer OSM3 by Kestrel Labs, or for the use of any service parts or solutions provided by Kestrel Labs.