DATREND Systems Inc.

Testing Masimo rainbow® Technology with vPad-A1

1. Background

1.1 Pulse Oximetry

Pulse oximetery measures oxygen saturation or the ratio of *oxyhemoglobin* to the total amount of hemoglobin in the arterial blood. A pulse oximeter transmits **RED** and **INFRARED** light through a part of the body such as an earlobe or finger and then measures the absorbance of the light at each wavelength (FIG. 1). The pulse oximeter calculates the ratio of the two absorbances to arrive at an estimate of the percent oxygen saturation, or % "***SpO2***".

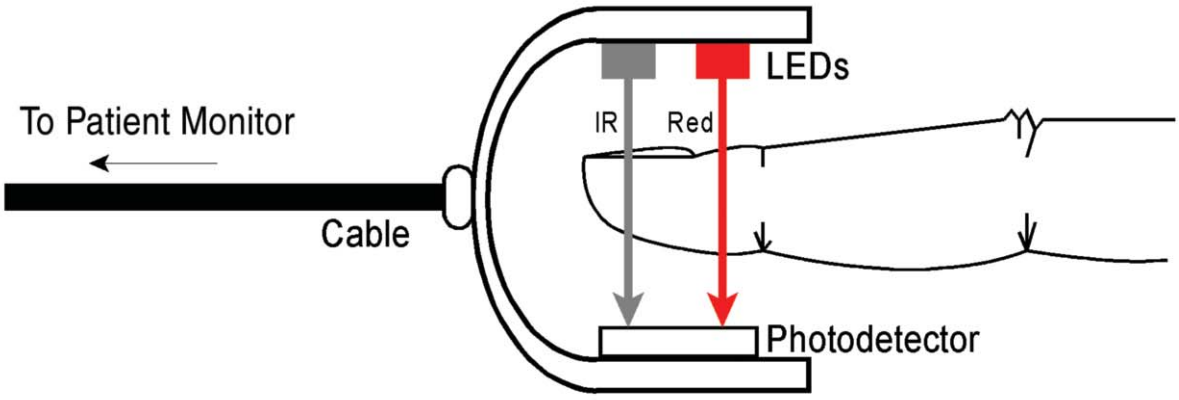

FIG. 1

1.2 Masimo rainbow® CO-Oximetry®.

Masimo rainbow® refers to a proprietary technology developed by Masimo Corporation for monitoring of SpO2 as well as representative measures of *methemoglobin*, *carboxyhemoglobin* and *total hemoglobin* in the arterial blood.

Methemoglobin is normally present in the blood in small amounts. Abnormally elevated concentration of methemoglobin, caused by exposure to certain drugs or toxic agents, may place a patient at risk since methemoglobin cannot transport oxygen. High levels of methhemoglobin may cause a pulse oximeter to display *lower* than the true SpO2. Masimo refers to its rainbow-based measurement of methemoglobin as "***SpMet***".

Carboxyhemoglobin is hemoglobin which has become bound to carbon monoxide instead of oxygen. It is characteristic of carbon monoxide poisoning and/or tobacco smoking. High levels of carboxyhemoglobin may cause a pulse oximeter to display *higher* than the true SpO2. Masimo refers to its rainbow-based measurement of carboxyhemoglobin as "***SpCO***".

Total hemoglobin is the sum of all types of hemoglobin in the blood. Total hemoglobin may be monitored during transfusions or in certain surgical procedures where significant blood loss is possible. Masimo refers to its rainbow-based measurement of total hemoglobin as "***SpHb***".

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Unlike other measurements obtained by rainbow technology, SpHb is represented in grams per deciliter of blood (g/dl) rather than percent.

Instead of two wavelengths of light as used in conventional pulse oximetery, Masimo's rainbow technology uses more than seven wavelengths. Rainbow technology relies on a sensor which is similar in construction to a pulse oximeter sensor, but which contains a variety of LEDs of differing colours (FIG. 2).

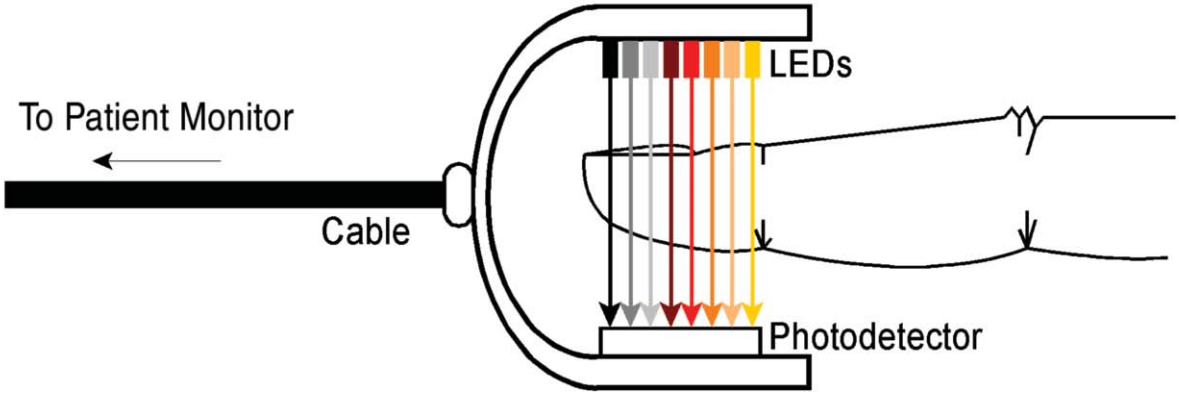

FIG. 2

Through methods similar to those of a conventional pulse oximeter, the rainbow monitor acquires absorbance signals for each wavelength and calculates SpO2, SpMet, SpCO and SpHb based on signal ratios. In addition to these measurements, a rainbow monitor may also determine a perfusion index ("***PI***") representing the quality of blood flow local to the sensor, and a total oxygen content or "***SpOC***" in ml/dl. Rainbow monitors calculate SpOC by means of a predetermined formula which combines the measured values of SpHb and SpO2. Similar to conventional pulse oximeters, rainbow monitors also indicate a pulse rate and may also display a real-time graph of a plethysmogram.

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2. Testing Rainbow Technology

2.1 Masimo Test Sensor

To enable routine maintenance inspections of rainbow monitors or patient monitoring systems which incorporate rainbow technology, Masimo has developed a testing method and a special sensor as shown in FIG. 3. The Masimo 3379 sensor is intended for use in conjunction with patient simulation devices which are able to test conventional two-wavelength pulse oximeters.

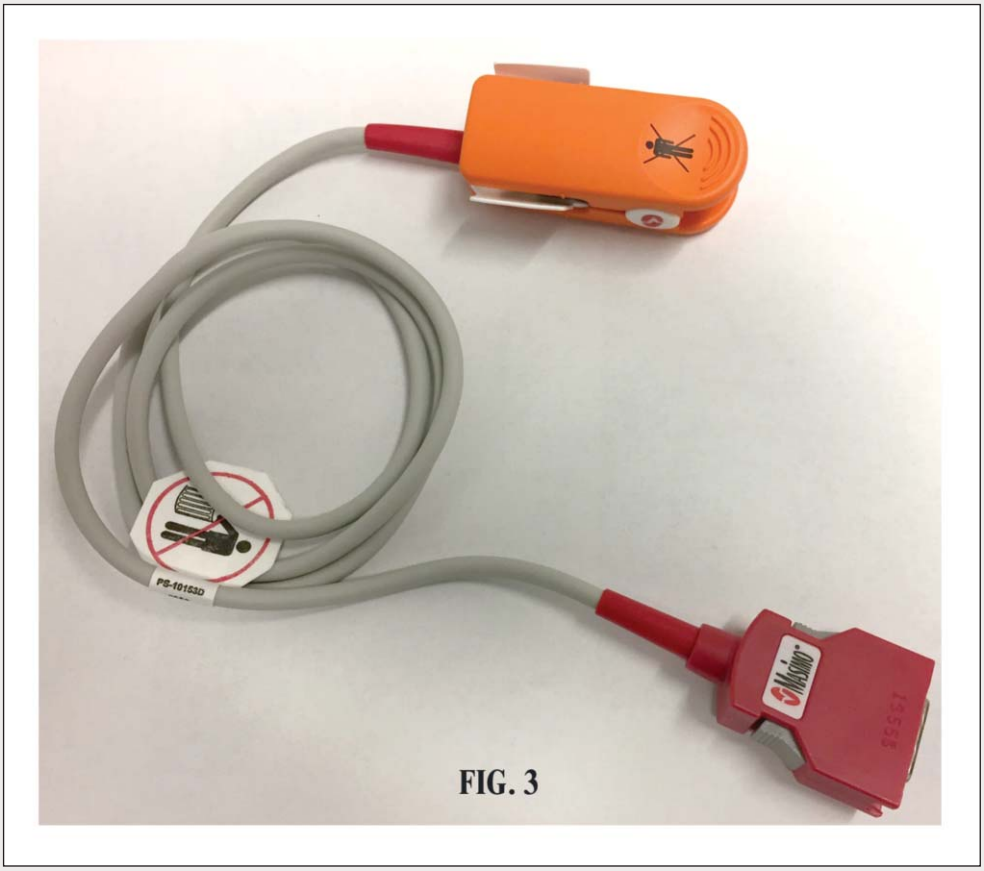

FIG. 3

Similar to a rainbow sensor, the 3379 sensor has a ***red*** multi-pin connector at one end which indicates it is meant to be used with a rainbow-enabled monitor such as the Masimo Radical-7®. The 3379 differs from a rainbow sensor in that it has an ***orange*** finger clip and a symbol that shows it must not be used on patients. The 3379 is internally wired so that rainbow-enabled monitors will recognize it.

To perform a test, the 3379 sensor is connected in place of the patient sensor and is applied to the probe of the pulse oximeter tester as shown in FIG. 4. Any pulse oximeter tester - such as Datrend's vPad-O2 module - may be used, provided the pulse oximeter tester incorporates the necessary calibration curves for SpO2, SpMet, SpCO, SpHb and SpOC as implemented in the 3379 test sensor.

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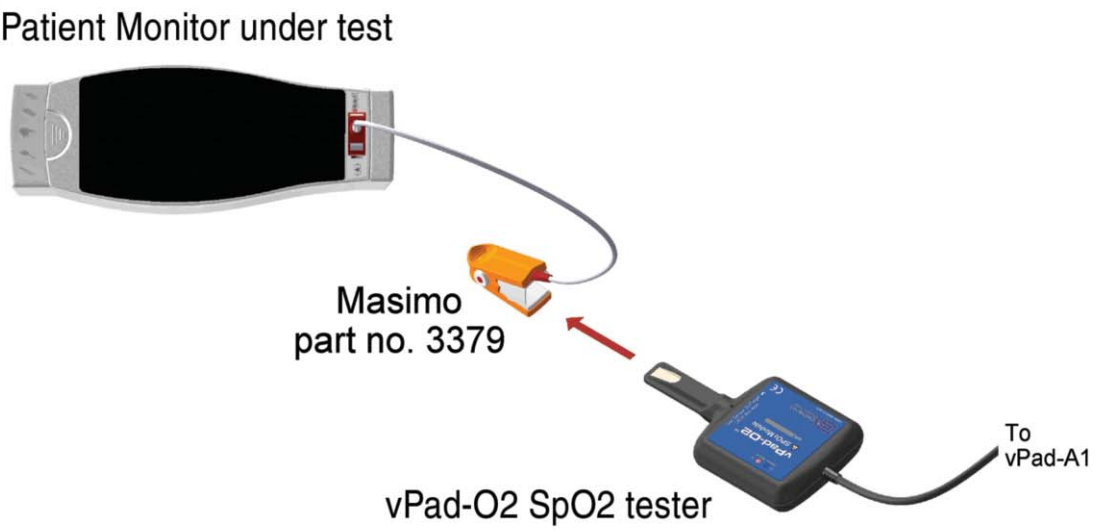

FIG. 4

2.2 Inspection Procedure for Masimo rainbow® Technology

Obtain a Masimo 3379 sensor and connect it to the patient monitor under test. Apply the 3379 sensor to the vPad-O2 pod as shown in FIG. 4. Note the sensor cable will face the labelled side of the pod. Connect the pod to the SPO2 jack of the vPad-A1 base unit.

Apply power to the vPad-A1 base unit and run the vPad-A1 software application or "app" on the tablet. Confirm the version number of the app as shown on the main menu is 1.10.0 or higher. If the version is less than 1.10.0, obtain an update by contacting your Datrend distributor or alternatively Datrend customer service (refer to contact information provided at the end of this application note).

Select the SPO2 tab on the main menu of the app, then select "Masimo" and "Rainbow" from the Manufacturer and Model dropdowns respectively. The app will prompt you to connect the Masimo 3379 sensor for the test. The app displays a rainbow icon near bottom right on the screen to indicate the rainbow test mode is enabled (FIG. 5).

FIG. 5

Set **Rate(BPM)** and **Ampl(%)** (pulse amplitude) to desired values. As a starting point, choose an amplitude of 100% and a rate of 60 BPM as shown in FIG. 5. After SpO2 and other hemoglobin measurements have been tested, rate and amplitude may be optionally varied to observe their respective effects on the monitor under test.

Select or enter a desired **SpO2**, for example 97% per FIG. 5. This will affect not only the SpO2 on the monitor, but also SpMet, SpCO, SpHb and SpOC. It is not possible to independently control SpMet and the other hemoglobin parameters as these are dependent on the SpO2 level and the preset characteristics of the 3379 sensor.

Press the **Result button** to view expected results for the selected **SpO2** level (FIG. 6). To view expected results for **SpMet**, **SpCO**, **SpHb** and **SpOC**, touch and drag the central part of the screen upward (FIG. 7).

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FIG. 6

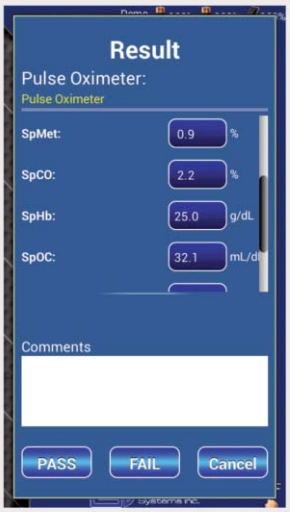

FIG. 7

The preset characteristics of the Masimo 3379 test sensor determine the response of a rainbow monitor as simulated SpO2 is varied. To summarize, when SpO2 is 100%, SbMet and SpCO should both be zero. As SpO2 is decreased below 100%, SbMet and SpCO should then increase by roughly 0.3% and 0.7% respectively for each percent decline in SpO2. SpHb should remain constant at 25 g/dl until SpO2 falls below 90%, at which point SpHb should then decrease by roughly 1 g/dl for each 2% decrease in SpO2. SpOC is derived from measured SpO2 and SpHb according to a formula which may be found in the Masimo literature.

Measurements displayed by the monitor should match the numbers shown on the Result screen of FIGs. 6 and 7 within specified tolerances. As a guideline, specifications for the Masimo Radical-7® monitor are shown in TABLE 1; for the particular monitoring device and software revision which is under test, refer to the latest specifications provided by the manufacturer of the equipment (Masimo; Dräger; Fukuda Denshi; Philips; Physio Control; Welch Allyn; Zoll; or other).

TABLE 1
Masimo Radical-7 Specifications (per FDA 510(k) K0208038)

Measurement	Range of measurement	Accuracy of measurement
SpO2	0 - 100%	SpO2=60-80%: ±3% (infant to adult) SpO2=70-100%: ±2% (neonate to adult) SpO2 < 60%: accuracy not specified
SpMet	0 - 99.9%	SpMet=1-15%: ±1% (neonate to adult) SpMet > 15%: accuracy not specified
SpCO	0 - 99%	SpCO=1-40%: ±3% (infant to adult) SpCO > 40%: accuracy not specified
SpHb	0 - 25 g/dl	SpHb=7-17 g/dl: ±1 g/dl (paediatric or adult) SpHb < 7 g/dl: accuracy not specified SpHb > 17 g/dl: accuracy not specified
SpOC	1 - 100 ml/dl	Accuracy not specified

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FIG. 8

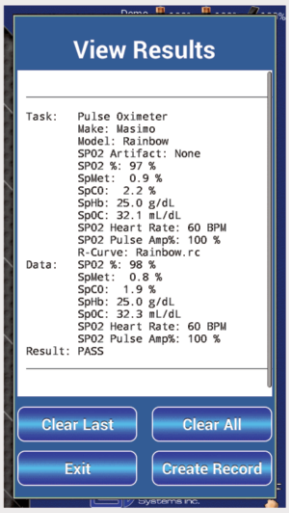

FIG. 9

If you wish to create a Test Record for the inspection, tap the corresponding field on the right of the screen to activate the numeric keypad (FIG. 8). Enter the actual value as displayed by the monitor, then repeat for the other displayed parameters. Optionally, a heart rate in BPM as shown by the monitor may also be entered. Compare the results to OEM specifications for the monitoring device and select **PASS** or **FAIL** at the bottom of the screen as appropriate. This will save the results to the test data buffer and return the app to the menu of FIG. 5.

While viewing the menu of FIG. 5, change the **SpO2** setting then repeat the steps as described above. Each choice of SpO2 will cause SpMet, SpCO, SpHb and SpOC to be set accordingly, following the characteristics of the 3379 sensor. To see how SpMet and other parameters are affected by the SpO2 level, press the **Result** button. If a Test Record is desired, enter the monitor's readings into the corresponding fields on the screen and press **PASS** or **FAIL** as appropriate.

Results saved to the data buffer may be viewed with the **View Results** button (FIG. 9). Recorded results will include the expected values for each parameter, along with the corresponding values observed from the display of the monitor as input by the user during the test. If desired, a permanent Test Record of the inspection results may be saved with the **Create Record** button.

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