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# Post marketing study of hemodynamic and hematological noninvasive readings in a blood bank

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## Abstract

**Objectives:** This validation test was conducted in the Fujisan Blood Bank, Fortaleza, Brazil and evaluated the noninvasive TensorTip MTX (MTX, Cnoga Medical Ltd.) readings of hemoglobin, hematocrit, red blood cells, blood pressure, and heart rate compared to reference lab device readings. Generally, these parameters are measured from venous or capillary blood samples run on a laboratory analyzer or handheld invasive testing devices. Needle sticks are inconvenient to blood donors with relatively high exposure risks. To our vision, noninvasive determination would be of benefit to blood contributors and medical professional teams; it would be fast and painless.

**Methods:** A total of 334 subjects were included in the Fujisan blood bank validation (65% male, 35% female). Hemoglobin, hematocrit, and red blood cells, as well as blood pressure and heart rate, were measured noninvasively using the MTX device and were compared to venous blood samples run on two laboratory hematology analyzers (Horiba ABX Micros60 and Siemens blood count analyzer), to digital sphygmomanometer (OMRON BP786) and to manual auscultation. The noninvasive measurement with the appropriate virtual arm cuff setting was performed simultaneously with the blood sample extraction of the reference devices measurement.

**Results:** There was no statistically significant difference ($p > 0.05$, paired, two-tailed *t*-test) between the average daily hemoglobin, hematocrit, and red blood cells measurements provided by the MTX device and the laboratory hematology analyzer. In addition, there was no significant difference between the daily blood pressure and heart rate results provided by the MTX device and the digital and manual sphygmomanometers. The error calculated between the MTX and the reference device was found to be sufficiently accurate according to the relevant standards.

**Conclusion:** The MTX accuracy of noninvasive hemoglobin, hematocrit, red blood cells, blood pressure, and heart rate measurements satisfies the industrial standards; therefore, the device enables more accurate, efficient, and effective patient care.

## Keywords

Cnoga Medical, TensorTip MTX, hemodynamics, hematology, hemoglobin, hematocrit, red blood cells, blood pressure, heart rate, monitoring, noninvasive, optical, imaging

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## Introduction

The standard measurement of hemoglobin, hematocrit, and red blood cells (Hgb, HCT, and RBC consequently) involves venipuncture or finger-prick, both of which are invasive methods that may cause pain and create a potential risk of infection for patients.[1,2] The need for convenient hematological blood monitoring devices has led to the development of alternative technologies, including the continuous and noninvasive monitoring. The ability to measure Hgb, HCT, and RBC noninvasively can allow a more rapid assessment of a patient's condition, enabling prompt and appropriate clinical management.

So far, several noninvasive methods, including clinical laboratory imaging system incorporating microscope lens system, a camera and a computer, and a noninvasive device based on differential light absorption, have been proposed.[3,4] Although, none of the technologies provide a satisfactory solution, the first for being available only in clinical laboratories due to its complex instrumentation, and the second due

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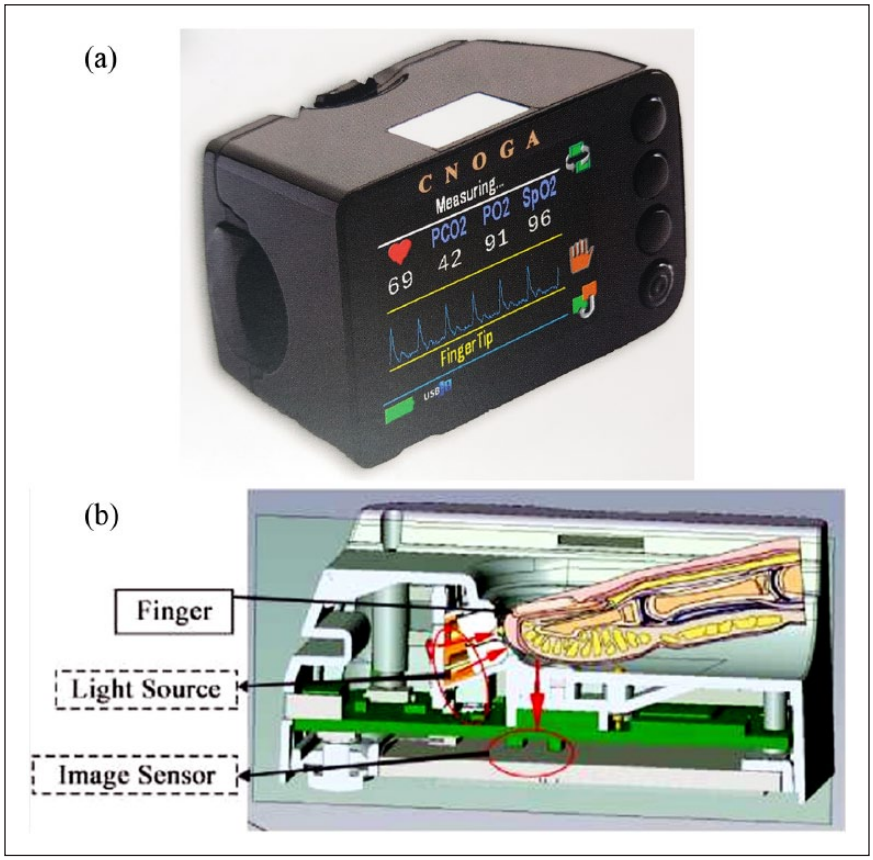


**Figure 1.** (a) The TensorTip MTX device and (b) a cross-sectional view of the TensorTip MTX.[15–17]

to its immobile monitor and its capability of measuring only three parameters.

There are increasing numbers of compact point of care or wearable noninvasive devices either already in the market or under development. These devices generally measure one or two parameters.[5] Most of current devices are based on the Pulse CO-Oximetry technology.[6–10] Pulse oximeters employ only two wavelengths of light and thus can distinguish only two bio-parameters, Hgb and $O_2$Hgb.[11] In addition, there are currently wearable consumer devices that measure heart rate (HR),[12] and wearable cuff-less blood pressure (BP) monitors that are under development.[13,14] Therefore, it is clear that there is a clinical need for a single device that provides measurements of Hgb, HCT, and RBC as well as BP and HR in a noninvasive manner.

The TensorTip MTX (MTX, Cnoga Medical Ltd., https://cnogacare.co) is a handheld, lightweight fingertip device with a measuring technique based on optical technology of real-time color image sensor. The color image sensor of the MTX enables a wide range of temporal-spatial-color information resulting in a more detailed resolution (Figure 1(a) and (b)).

The MTX device has been previously analyzed for accuracy in measuring hemodynamic BP and Hgb noninvasively and was found to produce accurate, repeatable readings.[18–20]

The aim of the current evaluation was to assess the concordance of Hgb, HCT, RBC, BP, and HR obtained noninvasively via the MTX with the values obtained from current laboratory methods.

## Methods

Three parameters were examined to ensure the post marketing success:

1. Accuracy of each bio-parameter reflects the industrial standard. Systolic and diastolic BP were compared to accuracy requirements of ISO 81060-2. Hgb accuracy was compared to Masimo Radical-7 marketed device. HR accuracy was compared to the reference device, Nonin 9590 pulse oximeter cleared device, and to ISO 9919 recognized standard. No industrial standard exists for HCT and RBC in the market nor other noninvasive devices for adequate comparison and analysis.
2. Suitable for blood bank use, that is, user experience.
3. Connectivity: Bluetooth, USB or Wi-Fi connectivity, measurement period, cost, support, maintenance.

These criteria were discussed with the blood bank team before executing the post marketing evaluation. Accuracy is

not the sole factor for the final decision. Decision for using this device in a blood bank also requires satisfactory business model for both sides.

### Participants

This prospective evaluation was performed in the Fujisan Blood Bank, Fortaleza, Brazil, during April 2016. Measurements were performed on 334 consecutive healthy blood donors >18 years old with normal range values (Hgb—females: 11–16 g/dL, males: 11.9–19 g/dL; HCT—females: 32–47%, males: 32–53%; RBC—females: 3–5 $10^6/mm^3$, males: 3.43–6 $10^6/mm^3$; BP—females: 80/50–120/90 mmHg, males: 100/60–140/90 mmHg; HR—females: 52–97 beats/min, males: 48–111 beats/min), 65% male and 35% female who entered the clinic to donate blood. The sample size of the MTX device was selected by the Fujisan Blood Bank based on the blood volunteers' availability. The inclusion criteria included healthy blood donors >18 years old. Patients with injured skin or perfusion disorder in the measurement site, unsuitable finger, or long fingernails were excluded from the study. In total, 11.4% participants were excluded due to improper perfusion during the measurement, 5.7% due to incorrect selection of the virtual arm cuff, and one male patient (0.3%) was excluded due to incompatibility of the finger. The final analysis included 180 males (65%) and 96 females (35%), giving altogether a total of 276 blood donors incorporating 1375 measurements for all blood parameters (as detailed in Table 4 in the "Results" section).

### Device

The experimental device used was the MTX. The device is described in more detail elsewhere.[18] Briefly, the device is intended for use in the home environment as well as clinics. The MTX device contains medical subsystem that is comprised of a color image sensor, light emitting diodes (LEDs), and a digital signal processor (DSP), which is responsible for the image acquisition, image processing, the lighting control system, and the extraction of the clinical parameter values. The device contains a finger compartment, four monochromatic light sources in the visual to infrared (IR) spectrum (~600 to ~1000 nm), and a color image sensor which is sensitive to a continuous spectrum in the range of ~380 up to ~1000 nm and provides the ability to analyze tissue pigmentation over the spatial-temporal-color domain using the light that traverses the finger's tissue. To date, the MTX is capable of measuring a total of 14 bio-parameters noninvasively, including mean arterial pressure (MAP), pH, blood gases, cardiac output, stroke volume, and additional parameters.

### Measurements

Investigators recorded the Hgb, HCT, and RBC as well as BP and HR as determined noninvasively by the MTX on the patient's ring finger according to the Instructions for Use. Blood samples were taken and analyzed using two laboratory blood count reference devices: Horiba ABX Micros60 (HORIBA ABX SAS, http://www.horiba.com) and Siemens blood count analyzer (Siemens Healthcare, https://www.healthcare.siemens.com). One simultaneous blood sampling was performed by each of the reference devices for each patient. BP and HR results provided by the MTX were compared to digital sphygmomanometer (OMRON BP786, Omron Healthcare, Inc., https://omronhealthcare.com) and manual auscultation. The most agreeable result of the reference devices was compared to the MTX measurement.

### Statistical analysis methods

For systolic and diastolic BP, the mean value of the differences of the determinations, $\bar{x}_n$, was calculated by the equation

$$\bar{x}_n = \frac{1}{n} \cdot \sum_{i=1}^{n} \left( \mathrm{BP}_{iMTX} - \mathrm{BP}_{iRef} \right) \tag{1}$$

where $n$ is the number of paired measurements of BP measured by the MTX ($\mathrm{BP}_{iMTX}$) and the reference ($\mathrm{BP}_{iRef}$), and $i$ is the index for the individual element.

The standard deviation, $s_n$, was calculated by the equation

$$s_n = \sqrt{\frac{1}{n-1} \cdot \sum_{i=1}^{n} \left( x_i - \bar{x}_n \right)^2} \tag{2}$$

where $x_i = (\mathrm{BP}_{iMTX} - \mathrm{BP}_{iRef})$.

Calculations are according to ISO 81060-2 applicable standard, section 5.2.4.2.2.

HR accuracy was calculated according to the equation

$$\mathrm{A}_{RMS} = \sqrt{\frac{\sum_{i=1}^{n} \left( \mathrm{HR}_{iMTX} - \mathrm{HR}_{iRef} \right)^2}{n}} \tag{3}$$

where $\mathrm{A_{RMS}}$ is the Root Mean Square of HR measured by the MTX ($\mathrm{HR}_{iMTX}$) and the reference ($\mathrm{HR}_{iRef}$), $i$ is the index of the individual element, and $n$ is the number of paired measurements of HR.

Calculation is according to ISO 9919 recognized standard, section 50.104, and Nonin 9590 pulse oximeter cleared device manual.[21]

HCT and RBC accuracies were calculated by the Normalized Mean Absolute Relative Difference (NMARD)

$$\mathrm{NMARD} = \frac{1}{n} \sum_{i=1}^{n} \frac{\left| MTX_i - Ref_i \right|}{Max\left( MTX_i, Ref_i \right)} \tag{4}$$

NMARD predicts the error in the range of 0% to 100%. In addition, measurements satisfying the following condition, $MTX_i \geq Ref_i$, were marked as Positive Normalized Mean Relative Difference (NMRD), which was calculated by

$$\text{Positive NMRD} = \frac{1}{n}\sum_{i=1}^{n}\left(\frac{\left(MTX_i - Ref_i\right) \geq 0}{Max\left(MTX_i, Ref_i\right)}\right) \quad (5)$$

Measurements satisfying the complementary condition, that is, $MTX_i < Ref_i$, were marked as Negative NMRD and were calculated as follows

$$\text{Negative NMRD} = \frac{1}{n}\sum_{i=1}^{n}\left(\frac{\left(MTX_i - Ref_i\right) < 0}{Max\left(MTX_i, Ref_i\right)}\right) \quad (6)$$

The average error $(\varepsilon)$ in substance concentration was calculated according to the equation

$$\begin{aligned} \varepsilon &= \frac{1}{n} \cdot \sum_{i=1}^{n} \varepsilon_i \cdot Max\left(Ref_i, MTX_i\right) \\ \varepsilon_i &= \frac{\left|Ref_i - MTX_i\right|}{Max\left(Ref_i, MTX_i\right)} \end{aligned} \quad (7)$$

Positive and negative $\varepsilon$ were calculated using the same mathematical rules as in equations (5) and (6); where $n$ is the number of paired measurements of HCT or RBC, $i$ is the index of the individual element of HCT or RBC, and $Max(MTX_i, Ref_i)$ is the maximal value between $(MTX_i)$ and the reference measurement $(Ref_i)$.

Hgb accuracy was calculated by the Mean Absolute Difference (MAD)

$$\text{MAD} = \frac{1}{n}\sum_{i=1}^{n}\left|Hgb_{MTX_i} - Hgb_{Ref_i}\right| \quad (8)$$

The calculation is according to Masimo Radical-7 marketed device[1,22] and previous comparative evaluation;[19] where $n$ is the number of paired measurements of Hgb, and $i$ is the index of the individual element of the MTX measurement $(Hgb_{MTX_i})$ and the reference devices measurement $(Hgb_{Ref_i})$.

Positive and negative diffusions were calculated by

$$Positive\ Diffusion = \frac{\begin{matrix}Total\ measurements\ with \\ Positive\ difference\end{matrix}}{Total\ \ participants} \quad (9)$$

$$Negative\ Diffusion = \frac{\begin{matrix}Total\ measurements\ with \\ Negative\ difference\end{matrix}}{Total\ \ participants} \quad (10)$$

Paired, two-tailed $t$-test[23] analysis was performed for each trial day. The test was performed on daily MTX measurements against the reference devices measurements. For the parameters which differ significantly ($p < 0.05$) between males and females group, the equivalent analysis was performed separately for each group to eliminate the interference of the background difference between the two genders, that is, Hgb, HCT, RBC, and BP.

Bland–Altman[24] analysis was performed on the hematological parameters, Hgb, HCT, and RBC. The bias was calculated according to the equation

$$bias = \frac{1}{n}\sum_{i=1}^{n}\left(Ref_i - MTX_i\right) \quad (11)$$

where $n$ is the total number of paired measurements of Hgb, HCT, or RBC; $i$ is the index of the individual pair of reference—$(Ref_i)$ and $(MTX_i)$—measurements.

The level of agreement (LoA) was calculated according to the equation

$$LoA = bias \pm 1.96 \cdot s_n\left(bias\right) \quad (12)$$

Passing–Bablok[25] regression was performed on Hgb and RBC parameters using MedCalc statistical software. All other calculations and graphs were made using Excel 2013, Office.

## Results

Readings of Hgb, HCT, RBC, BP, and HR were analyzed from 276 healthy participants. The MTX measurements were compared to the most agreeable laboratory blood count reference device. BP and HR results provided by the MTX were compared to digital sphygmomanometer and manual auscultation.

Paired, two-tailed $t$-test was the initial statistical test used for assessing the agreement between the methods. The calculated $p$-value indicated insignificant difference in HR values between males and females. Hgb, HCT, RBC, and BP gave significantly different values for each of the genders; hence, the $p$-value was calculated separately for males and females in these parameters. Table 1 displays the average of the daily $p$-value for each blood parameter. The $t$-test analysis was concluded on a daily basis (see Table 1 in Supplemental Material). Daily information provides higher resolution of the device operation. For example, day 8 $t$-test performed for the RBC failed to pass $p$-value for both female and male. This sort of information enables a better insight into the nature of the constrains, that is, weaknesses versus strengths.

In addition, the MTX readings were averaged and compared to the reference average result. Table 2 displays the average $(\bar{x}_n)$ and the standard deviation $(s_n)$ of each of the parameters measured by the MTX device and the reference devices. As can be seen, there were equivalent results for the MTX and the reference devices given close enough average results and deviation.

**Table 1.** Averaged daily *p*-value of the blood parameters.

| | Group | *t*-test paired *p*-value |
|---|---|---|
| Hgb | Female | 0.42 |
| | Male | 0.55 |
| HCT | Female | 0.40 |
| | Male | 0.37 |
| RBC | Female | 0.41 |
| | Male | 0.27 |
| BP systolic | Female | 0.47 |
| | Male | 0.48 |
| BP diastolic | Female | 0.55 |
| | Male | 0.49 |
| HR | No difference | 0.82 |

Hgb: hemoglobin; HCT: hematocrit; RBC: red blood cells; BP: blood pressure; HR: heart rate.

**Table 2.** Average and standard deviation of blood parameters measured by the MTX in comparison to the reference devices.

| | Group | MTX $\bar{x}_n \pm s_n$ | Reference $\bar{x}_n \pm s_n$ |
|---|---|---|---|
| Hgb | Female | 13.15 ± 1.40 | 13.26 ± 0.89 |
| | Male | 15.28 ± 1.55 | 15.38 ± 1.01 |
| HCT | Female | 42.11 ± 4.33 | 40.15 ± 2.81 |
| | Male | 47.70 ± 4.57 | 45.97 ± 2.63 |
| RBC | Female | 4.54 ± 0.61 | 4.54 ± 0.33 |
| | Male | 5.34 ± 0.59 | 5.23 ± 0.41 |
| BP systolic | Female | 102.50 ± 7.25 | 105.10 ± 6.96 |
| | Male | 123.18 ± 11.54 | 120.78 ± 9.21 |
| BP diastolic | Female | 65.83 ± 7.06 | 67.71 ± 7.47 |
| | Male | 79.33 ± 9.03 | 78.00 ± 6.72 |
| HR | No difference | 74.19 ± 10.75 | 73.97 ± 9.41 |

$\bar{x}_n$, average; $s_n$, standard deviation; Hgb: hemoglobin; HCT: hematocrit; RBC: red blood cells; BP: blood pressure; HR: heart rate.

The results were further analyzed and compared according to the Bland–Altman graphical analysis (Figure 2). The plots describe the difference between paired measurements of the reference device and the MTX versus the average of the two values. The analysis revealed a bias of 0.08 g/dL, 1.13%, and 0.31 $10^6/mm^3$ in Hgb, HCT, and RBC correspondingly. The calculated 95% LoA boundaries of Hgb were from −2.52 to 2.69 g/dL, of HCT from −7.13% to 9.39%, and of RBC from −0.81 to 1.43 $10^6/mm^3$.

Hgb and RBC are fundamental parameters usually measured for diagnosing anemia and other diseases; therefore, their accordance to the reference results was confirmed also by the Passing–Bablok test (Figure 3). The linear regression equation for Hgb was fitted as $y = -5.662 + 1.375x$. The linear regression equation for RBC was fitted as $y = -2.632 + 1.493x$. The fitted linear equations, intercept (95% confidence interval (CI)), and slope (95% CI) are shown in Table 3. The linear equations were all well fitted (all $ps > 0.10$).

Table 4 depicts the error calculated between the results obtained from the MTX device as compared to the reference devices. Each parameter has its own error calculations according to its standard.

## Discussion

In the current evaluation, the feasibility of the use of a new, compact, noninvasive device for the spot check measurement of HR, BP, Hgb, HCT, and RBC count was demonstrated. The device is cleared for BP and HR by the US Food and Drug Administration (FDA); all other parameters are certified in 38 countries among them: CMDCAS (Canada), ANVISA (Brazil), CFDA (China), CE (Europe), and Israel (AMAR).

The noninvasive MTX device was compared to the invasive reference devices using a daily *t*-test analysis, enabling more accurate and detailed analysis. A daily *t*-test takes into consideration the interfering factors such as human and environmental factors or noises which are part of the daily situation that may interfere with the noninvasive measurements. For instance, in a cold day a heater is on and in a warm day an air conditioner is on. Human factors, such as emotion, physical activity, clothing, after or before meal, and so on, may affect the reading. Therefore, the daily *p*-value produces a better resolution analysis and enables us to understand why in a certain day *t*-test may fail as shown in Table 1 in Supplemental Material. In this way, the user is being informed in the Instructions for Use on the potential constrains while the developer is looking for ways to improve the device performance. According to the average results, it can be seen that the device is equivalent to nowadays marketed reference devices used ($p > 0.05$) with some deviations on daily basis.

Moreover, the average and standard deviation of blood parameters calculated for both the MTX and the reference results show an acceptable accordance between the devices. Previous studies showed that the MTX device was found to produce accurate and repeatable noninvasive results of hemodynamic BP and Hgb.[18,19] Current evaluation confirmed our previous findings and conformed to the requirements of ISO 81060-2. The mean value of the differences of the determinations, $\bar{x}_n$, was also in the accepted range for both the systolic and diastolic BP.

The MTX device provided Hgb accuracy better than 1 g/dL as previously presented.[1,22] Moreover, previous study performed by the Chinese PLA General Hospital staff showed that the MTX device provided a better accuracy than other noninvasive marketed devices when separately compared to the clinical laboratory hematology analyzer, a Sysmex XN9000 (Jinan Sysmex Medical Electronics Co. Ltd., Shanghai, China).[19] Bland–Altman analysis for Hgb

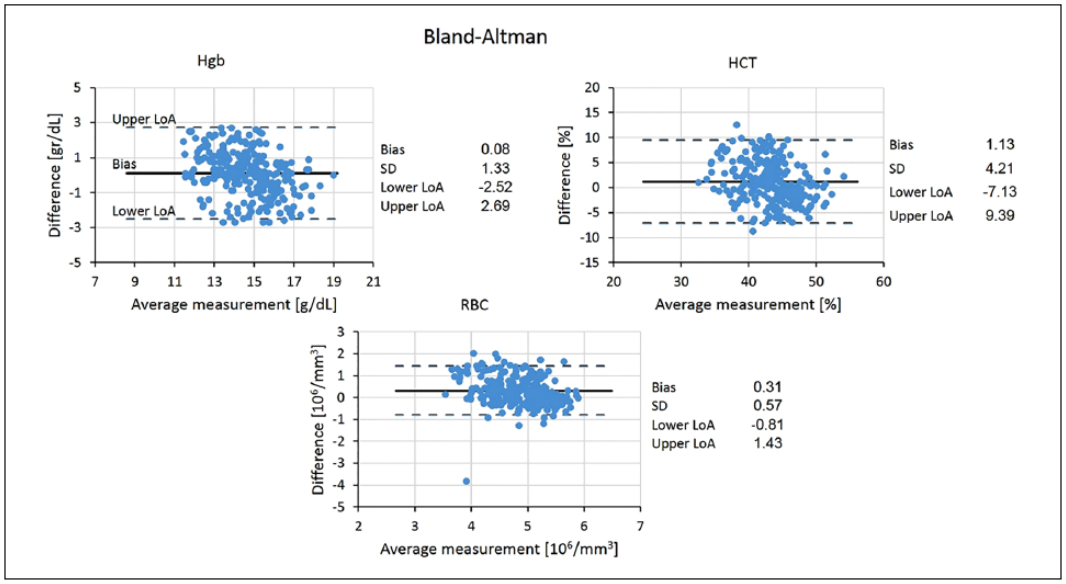


**Figure 2.** Bland–Altman comparison of Hgb, HCT, and RBC. The *x*-axis represents the average of the MTX and reference measurements, and the *y*-axis represents the difference (Reference−MTX). The bias and LoA are shown in horizontal lines. The long bolded and solid line is drawn at the mean difference; dashed lines are drawn at the mean difference ±1.96 times the standard deviation of the mean difference.

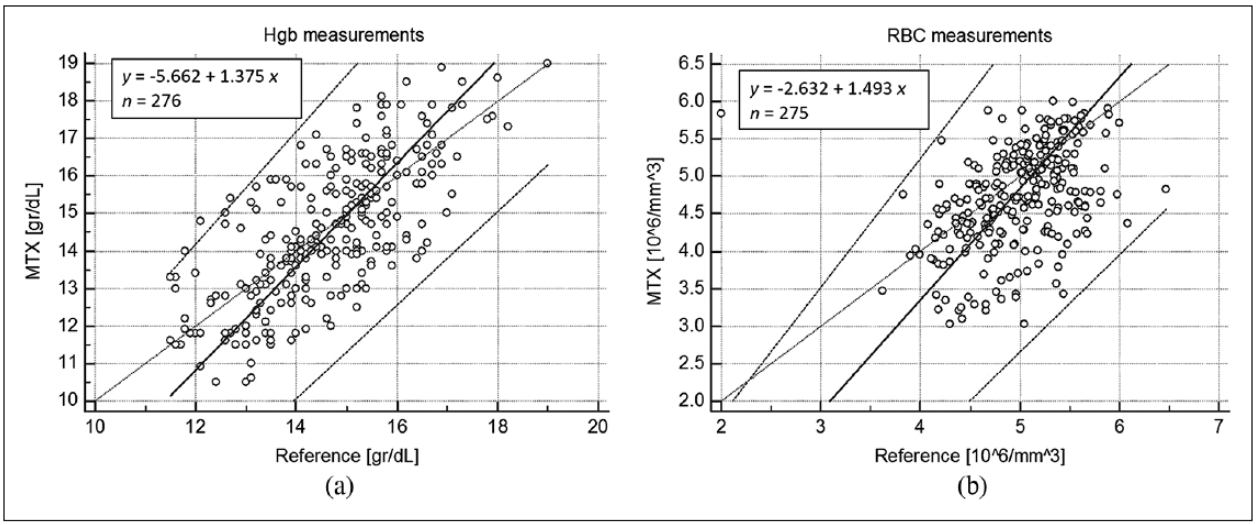


**Figure 3.** Scatter diagram and linear regression analysis of (a) Hgb comparison between the MTX and the reference results and (b) RBC comparison between the MTX and the reference results, using Passing–Bablok regression analysis. Solid line—the regression line; dashed lines—the CI for the regression line; $x = y$, dotted line—the identity line.

also demonstrated a slightly better agreement than other marketed devices.[22]

HR accuracy was compared to the reference device, Nonin 9590 pulse oximeter cleared device,[21] and to ISO 9919 recognized standard, and fulfilled the requirement of ±3 digits tolerance.

The values obtained for both HCT and RBC imply on sufficiently accurate results. However, no industrial standard exists in the market nor other noninvasive devices for adequate comparison and analysis.

Since RBC and Hgb are vital parameters usually measured for diagnosing anemia and other diseases, they were further confirmed by the Passing–Bablok test. The Passing–Bablok regression analysis showed good agreement between the MTX and the reference measurements with $p > 0.1$, indicating a linear relationship between the measurements in both methods.

This evaluation represents sufficiently accurate measurements of healthy blood donors with normal range values. Therefore, extreme cases were not evaluated in this study due to the fact that all blood donors were healthy. Yet, this

**Table 3.** Passing–Bablok regression analysis equations of the comparison between the MTX and the reference results of Hgb and RBC.

| | Passing–Bablok equation | *a* (95% CI) | *b* (95% CI) | *p*-value |
|---|---|---|---|---|
| Hgb | $y = -5.662 + 1.375x$ | −5.662 (–7.4500 to −3.8250) | 1.375 (1.2500 to 1.5000) | $p > 0.1$ |
| RBC | $y = -2.632 + 1.493x$ | −2.632 (–3.8293 to −1.6617) | 1.493 (1.2959 to 1.7248) | $p > 0.1$ |

Hgb: hemoglobin; RBC: red blood cells; CI: confidence interval; *a*: intercept *a; b*: intercept *b*.

**Table 4.** MTX concordance to the reference devices measurements.

| Parameter | Number of measurements | Calculated error |
|---|---|---|
| Hgb | 276 | $MAD = 0.99\,g/dL$ |
| HCT | 274 | $NMARD = 8.18\%$ |
| | | $Positive\,NMRD = 5.85\%$ |
| | | $Negative\,NMRD = -2.33\%$ |
| | | $Pos\,diffusion = 0.69$ |
| | | $Neg\,diffusion = 0.31$ |
| RBC | 275 | $\varepsilon = 0.52\frac{10^6}{mm^3}$ |
| | | $Positive\,\varepsilon = 0.27\frac{10^6}{mm^3}$ |
| | | $Negative\,\varepsilon = -0.23\frac{10^6}{mm^3}$ |
| | | $Pos\,diffusion = 0.61$ |
| | | $Neg\,diffusion = 0.39$ |
| Systolic BP | 275 | $\bar{x}_n = 0.65\,mmHg$ |
| | | $s_n = 7.94\,mmHg$ |
| Diastolic BP | 275 | $\bar{x}_n = 0.15\,mmHg$ |
| | | $s_n = 4.89\,mmHg$ |
| HR | 275 | $A_{RMS} = 3.00\,beat/min$ |

Hgb: hemoglobin; HCT: hematocrit; RBC: red blood cells; BP: blood pressure; HR: heart rate.

test was sufficient for blood donors since blood would not be taken from participants with abnormal blood parameter values. Nonetheless, the device still has some limitations in case of low perfusion which are planned to be resolved by an automatic calibration of the device according to the perfusion of the finger. Moreover, patients with injured skin, unsuitable finger, or long fingernails could not participate in the study. Other studies of this device on more extreme cases corroborate the device validity.[20]

Based on current results, the MTX offers for the first time a simple and accurate noninvasive way to measure blood parameters. It is clear that this compact noninvasive device will have many useful applications.

## Conclusion

In conclusion, at these days there is an immense need for convenient, noninvasive hemodynamic and hematological blood monitoring devices. None of the technologies available today provide the ability of measuring noninvasively Hgb, HCT, and RBC as well as BP and HR in a single device. The MTX being capable of measuring up to 14 bio-parameters would help facilitating patients' life by being available for individuals in their comfort home as well as for clinics. The MTX provides the ultimate solution for the growing need of fast, pain-free monitoring devices in remote medicine, rural areas, community clinics, and home.

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### Declaration of conflicting interests

The author declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Y.(J.)S. is the inventor of the presented TensorTip CoG technology, and founder and a shareholder of Cnoga Medical Ltd., the company commercializing the related product.

### Ethical approval

The MTX is an ANVISA cleared device to be marketed in Brazil. The Brazilian blood bank wanted to check the feasibility of the device to be used in the blood bank. Due to the fact that the MTX is cleared to be marketed in Brazil, the blood bank was allowed to use the device for post marketing evaluation without the need for ethic confirmations. The evaluation was part of the blood bank routine operations, which require registration and blood tests of each blood volunteer. The company received the comparison raw data of the device versus the reference devices without any personal information of the volunteers. Therefore, waive by the IRB/IEC was not relevant.

### Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

### Informed consent

Since our device is ANVISA approved for marketing in Brazil, its records were taken by the blood bank in the routine operation. The measurements were performed as a post marketing examination by

the blood bank and not as a pre-study clinical trial. No personal information was delivered to the company nor any information connecting raw data to each of the volunteers. Therefore, no informed consent or waive was relevant.

## Trial registration

Trial registration was not needed because the article describes a post marketing evaluation and not a clinical trial.

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