



November 7th, 2023

Subject: RNA Medical CVC 223 Range Update set lot 322342

Dear Valued Customer,

RNA Medical has been working with the original equipment manufacturer (OEM) of the Avoximeter models to determine the cause of the out-of-range recoveries noted in the field using controls from CVC223 set lot 322342. The creation of the Avoximeter expected values which are published on the data insert derive from the OEM's data analysis using historical field data in combination with in-house lab testing. Following the review of the out-of-range communications along with a review of the data generation process, it was determined that an error in outlier analysis created incorrect bias data.

The data generation process has been corrected and new values are being provided for set lot 322342. The new ranges are on the second page of this notification letter.

We sincerely apologize for these errors and the difficulties you have experienced while awaiting this communication. We strive to provide high quality and positive experience with our RNA Medical products.

Change of values for part CVC223, lot 322342, exp date 2024-09-30 as of November 7, 2023.

PRODUCT:
 RNA CVC 223
 RNA CC 527
 RNA QC-253

LEVEL 1 N/A
 LOT:

35139

LEVEL 2 N/A
 LOT:

34873

LEVEL 3 N/A
 LOT:

34969

Analyte	Unit of Measure	Instrument	Mean	Lower Limit	Upper Limit	Mean	Lower Limit	Upper Limit	Mean	Lower Limit	Upper Limit
tHb	g/dL	AVOXimeter 1000E	5.5	4.9	6.1	8.5	7.8	9.2	13.6	12.5	14.7
O ₂ Hb	%		33.3	28.7	37.9	94.1	89.6	98.6	83.0	78.7	87.3

tHb	g/dL	AVOXimeter 4000/ GEM OPL	5.5	4.9	6.1	8.2	7.5	8.9	13.3	12.2	14.4
O ₂ Hb	%		33.1	28.5	37.7	95.1	90.6	99.6	83.9	79.6	88.2
COHb	%		68.1	61.1	75.1	7.3	3.3	11.3	17.5	13.0	22.0
MetHb	%		-0.2	-3.1	2.7	0.0	-2.9	2.9	0.1	-2.9	3.0

LEVEL 4 N/A
 LOT:
 35066

LEVEL 5 N/A
 LOT:
 35242

Analyte	Unit of Measure	Instrument	Mean	Lower Limit	Upper Limit	Mean	Lower Limit	Upper Limit
tHb	g/dL	AVOXimeter 1000E	17.3	16.0	18.6	22.2	20.0	24.4
O ₂ Hb	%		55.3	51.0	59.6	4.6	-3.4	12.6

tHb	g/dL	AVOXimeter 4000/ GEM OPL	17.1	15.8	18.4	22.1	19.9	24.3
O ₂ Hb	%		55.5	51.2	59.8	2.7	-5.3	10.7
COHb	%		45.5	40.2	50.8	ORL	ORL	ORL
MetHb	%		0.3	-2.6	3.2	0.8	-2.1	3.7

If you have any questions, please feel free to reach out using the contact information below.

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