

**RAPIDPoint® 500 Blood Gas Systems
 RAPIDPoint® 500e Blood Gas Systems
 CVM® Calibration Verification Material**

Incorrect Performance Variability Ranges and Alternate Units Missing on CVM Material for the RAPIDPoint 500/500e Blood Gas Systems

Our records indicate that your facility may have received the following product(s):

Table 1. Affected Products

Product Description	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)	Affected Lot	Expiration Date (YYYY-MM-DD)
CVM (Calibration Verification Material)	10316535	00630414195131	350123	2025-05-31

Reason for Customer Notification

The purpose of this communication is to inform you of a potential issue with the product indicated in Table 1 above and provide instructions on actions that your facility must take.

Siemens Healthcare Diagnostics Inc. has confirmed that the Instructions for Use (IFU) of the CVM for the specific lot listed in Table 1 has incorrect performance variability ranges for pCO2 Level 1, Glucose Level 2, and Lactate levels 2, 3, and 5 for some measurement cartridge types and is missing the alternative units for the RAPIDPoint 500/500e with a lactate measurement cartridge.

The correct CVM ranges for lot 350123 are listed in Table 2 below. The published CVM material performance variability ranges for all other analytes are unaffected.

Incorrect Performance Variability Ranges and Alternate Units Missing on CVM Material
for the RP 500/500e Blood Gas Systems

Table 2. CVM Lot 350123 Correct Ranges

CVM Kit Lot #	System	Level	Analyte	Unit	Published Range (Incorrect)		Correct Range	
					Low	High	Low	High
350123	RAPIDPoint 500/500e (Blood Gas/Co-Ox Cartridge)	1	pCO2	mmHg	135.5	171.5	144.1	180.1
		1	pCO2	kPa	18.06	22.86	19.21	24.01
	RAPIDPoint 500/500e (with Lactate Cartridge)	2	Glu	mg/dL	176	212	175	211
		2	Lac	mmol/L	9.80	13.80	8.70	12.70
		3	Lac	mmol/L	0.66	1.14	0.60	1.08
		5	Lac	mmol/L	0.24	0.76	0.18	0.70

The missing CVM ranges for lot 350123 for use with the RAPIDPoint 500/500e (with Lactate Cartridge) are listed in Table 3 below. The published CVM material performance variability ranges for all other analytes are unaffected.

Table 3: CVM Lot 350123 Missing Ranges

CVM Kit Lot #	System	Level	Analyte	Unit	Range (Missing from the IFU)	
					Low	High
350123	RAPIDPoint 500/500e (with Lactate Cartridge)	1	H+	nmol/L	207.0	180.3
		1	pCO2	kPa	18.06	22.86
		1	pO2	kPa	8.87	11.80
		1	Ca	mg/dL	10.0	13.2
		1	tHb	g/L	197	221
		1	tHb	mmol/L	12.2	13.7
		1	Glu	mmol/L	32.4	41.6
		1	Lac	mg/dL	121.5	229.5
		1	nBili	µmol/L	357	494
		2	H+	nmol/L	85.9	74.8
		2	pCO2	kPa	8.52	11.88
		2	pO2	kPa	17.54	21.01
		2	Ca	mg/dL	5.3	6.6
		2	tHb	g/L	161	185
		2	tHb	mmol/L	10.0	11.5
		2	Glu	mmol/L	9.7	11.7
		2	Lac	mg/dL	78.3	114.3
		2	nBili	µmol/L	310	446
		3	H+	nmol/L	53.2	46.3
		3	pCO2	kPa	5.39	6.72
		3	pO2	kPa	12.49	15.16
		3	Ca	mg/dL	4.3	5.2
		3	tHb	g/L	126	146
		3	tHb	mmol/L	7.8	9.1
3	Glu	mmol/L	4.4	5.5		
3	Lac	mg/dL	5.4	9.7		

Incorrect Performance Variability Ranges and Alternate Units Missing on CVM Material
for the RP 500/500e Blood Gas Systems

		3	nBili	µmol/L	195	291
		4	H+	nmol/L	33.3	29.0
		4	pCO2	kPa	2.81	3.88
		4	pO2	kPa	3.51	7.77
		4	Ca	mg/dL	2.8	3.6
		4	tHb	g/L	65	81
		4	tHb	mmol/L	4.0	5.0
		4	Glu	mmol/L	1.9	3.1
		4	Lac	mg/dL	20.7	31.5
		4	nBili	µmol/L	65	147
		5	H+	nmol/L	19.8	17.3
		5	pCO2	kPa	1.27	2.65
		5	pO2	kPa	58.63	78.63
		5	Ca	mg/dL	1.9	2.7
		5	tHb	g/L	42	54
		5	tHb	mmol/L	2.6	3.4
		5	Glu	mmol/L	1.1	1.9
		5	Lac	mg/dL	1.6	6.3
		5	nBili	µmol/L		<34

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Replace the published CVM ranges from the original IFU with the correct ranges in Table 2 and/or the missing ranges in Table 3 for the RAPIDPoint 500/500e Blood Gas System.
- Keep this letter with your CVM records. If you utilize RAPIDComm® Data Management System or some other application to record and manage your CVM results, edit these ranges for this lot and replace with the correct ranges as listed above.
- If you are a distributor, please ensure your customers receive this letter.
- Please forward this letter to those who may have received this product in your facility.

The correct ranges listed in Table 2 and Table 3 are also available in Siemens Document Library.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Additional Information

CVM, RAPIDPoint, and RAPIDComm are trademarks of Siemens Healthcare Diagnostics Inc.

Siemens Healthcare Sdn. Bhd.
Registration No: 201501001338 (1126670-U)

Management: Roderick John Frazer, Managing Director; Jan Henning Tiedermann, Finance Director

Block A, Level 33A,
Menara The MET,
No 20 Jalan Dutamas 2,
50480 Kuala Lumpur

Tel: +603-6206 4945
siemens-healthineers.com/en-my