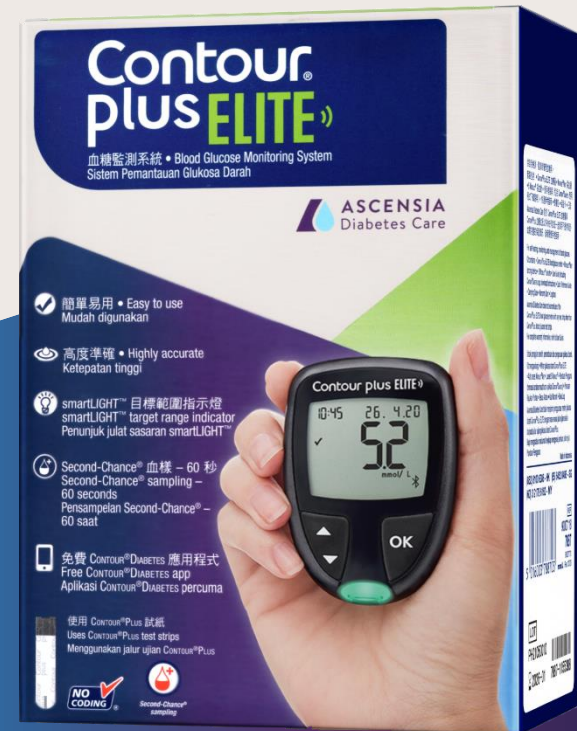




CONTOUR®PLUS ELITE BGMS Product Training

Highly accurate⁵ and easy. The features your patients want from a meter^{8,*}



The smartLIGHT[®] feature gives instant feedback on blood glucose readings



The CONTOUR[®]PLUS ELITE system has been shown to deliver high accuracy^{5,**}



Second-Chance[®] sampling countdown screen shows patients have 60 seconds to apply more blood to the same strip



- No Initial Set-up^{***}
- Personalized target ranges
- Averages on the meter



Large, easy-to-use rubber buttons



Free, optional CONTOUR[®]DIABETES app is easy to use and intuitive for patients

Trust the light



*Based on market research survey across 13 features (n=100 PWDs)

**An ad hoc analysis demonstrated that 95% of results fell within ± 8.4 mg/dL (± 0.46 mmol/L) or 8.4% of the laboratory reference values for glucose concentrations < 100 mg/dL (< 5.55 mmol/L) or ≥ 100 mg/dL (≥ 5.55 mmol/L), respectively, when tested via subject obtained capillary fingertip results (patients with diabetes)⁵

***Before use please read the CONTOUR[®]PLUS ELITE user guide for full instructions.



SmartLight and Target range

smartLIGHT® and target range* icons

- The meter displays the result with the units, time, date, enlight a strip port and show the target range icon on meter display
- A strip port light color and icon on meter display indicates if the reading is above, in, or below the personal target range



Below
Target Range
< 3.9 mmol/L



In
Target Range
3.9 mmol/L – 10.0 mmol/L



Above
Target Range
> 10.0 mmol/L

*Always consult your healthcare professional before setting or changing any target ranges

Change overall Target Range

1. Press and hold the OK button until the meter turns on. The Home screen has 2 options: **Logbook** and **Settings**.
2. To highlight the **⚙️ Settings** symbol, press the ▼ or ▲ button.
3. When the **⚙️ Settings** symbol is blinking, press the OK button to enter Settings.
4. Press the ▼ button repeatedly until the **Target symbol** **🎯** is blinking, then press the **OK** button. The meter displays the **Overall Low Target screen**.
5. To change the blinking **Low** end of the **Overall Target Range**, press the ▼ or ▲ button.
6. To set the **Low** end, press the **OK** button.
7. To change the blinking **High** end of the **Overall Target Range**, press the ▼ or ▲ button.
8. To set the High end, press the OK button. The meter returns to the Home screen.



WARNING

Discuss your Target Range settings with your health care professional.

CONTOUR®PLUS ELITE

Auto-calibration	Yes ()
Measurement Range mmol/L	0.6-33.3
Built-in Memory with Date and Time	800
Sample Type, C=cap ,V=ven, A=art, N=neo	C,V,A,N
Reference Method	Capillary Plasma Blood
No interference with maltose or galactose ¹	Regent chemistry system uses FAD-GDH which eliminates interference by maltose
Blood Volume	0.6 µL
Result	5 second countdown
ISO Fulfilled	ISO15197:2013 (EN ISO15197:2015)
Test Strip Name	CONTOUR®PLUS Test Strip
Operation Humidity	10-93 %
Operating Temperature	5-45 °C
Hematocrit Range	0-70 %
Strip Expiration After Opening	Till expiry date
Power	Two lithium batteries (CR2032)
Radio Frequency Technology	Bluetooth® Low Energy
Radio Frequency Band	2.4 GHz – 2.483 GHz
Languages	English
Test Principle	Measurement of electrical current caused by reaction of the glucose with the reagents on the electrode of the strip
Rated Operation	Continuous Operation Auto-start with strip insertion

1. Klaff L et.al. Accuracy and User Performance of a New Blood Glucose Monitoring System [published online ahead of print, 2020 Nov 26].J Diabetes Sci Technol. 2020; <https://doi.org/10.1177/1932296820974348>.

New ISO 15197:2013 Standards require tighter meter accuracy¹

ISO 15197:2013¹

accuracy standard require
95% of readings to be within

$\pm 15\%$ of the reference
for glucose levels
 ≥ 5.6 mmol/L

± 0.83 mmol/L of the reference
for glucose levels
 < 5.6 mmol/L

Report accuracy in the lab and in the
hand of patients

99% of blood glucose readings should
fall within zone A & B of Parkes
Consensus Error Grid

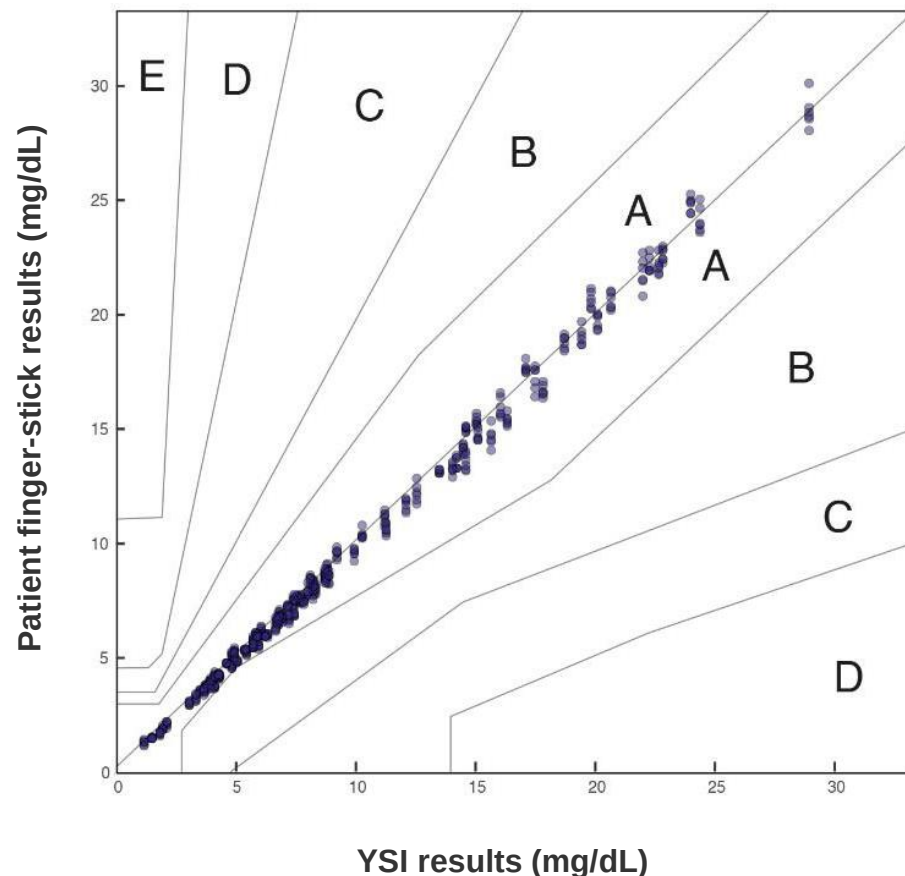
REFERENCES:

1. International Organisation for Standardization. In vitro diagnostics test systems requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus, Geneva, Switzerland: International Organisation for Standardization;2013.

Accuracy- Parkes-Consensus Error Grid analysis

Parkes-Consensus Error Grid analysis¹ showed that patient capillary finger-stick blood glucose measurements using CONTOUR®PLUS ELITE blood glucose monitoring system are clinically acceptable: 100% of results were within Zone A of the Parkes-Consensus Error Grid²

- Accuracy targets exceed current ISO accuracy criteria when performed by the intended users, both patients with diabetes and HCPs, and meet the proposed tighter ISO accuracy criteria^{2,3}



1. Parkes J, et al. Diabetes Care 2000;23:1143–8; 2. Klaff L et al. J Diabetes Sci Technol. November 2020. doi:10.1177/1932296820974348; 3. ISO 15197: In vitro diagnostic test systems – requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Revised first edition, 2003.

The CONTOUR® PLUS ELITE system shows remarkable accuracy

- The CONTOUR®PLUS ELITE system met the more stringent accuracy requirements of ISO 15197:2013^{*1,2}
- 100% of results were within zone A of the Consensus Error Grid²
- Accuracy was maintained, even at the tighter error limits such as $\pm 10\%$ or $\pm 0.56 \text{ mmol/L}$ ²

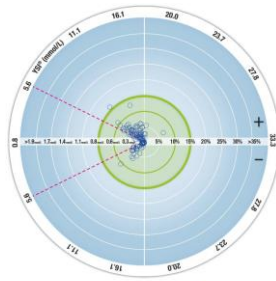
An ad hoc analysis demonstrated that **95 %** of the results were within the error range:

$\pm 0.47 \text{ mmol/L}$

or

$\pm 8.4 \%$

of the laboratory reference values for glucose concentrations $< 5.55 \text{ mmol/L}$ or $\geq 5.55 \text{ mmol/L}$, respectively, when tested via subject obtained capillary fingertip results (patients with diabetes)²



○ All samples (n = 128) — 0.6 mmol/L or 10% — 0.8 mmol/L or 15%

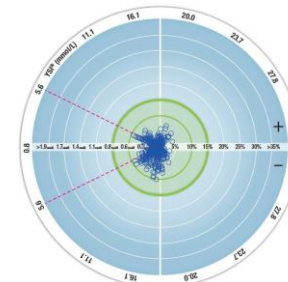
CONTOUR®PLUS ELITE system has demonstrated that **99.8 %** of the results were within the error range:

$\pm 0.56 \text{ mmol/L}$

or

$\pm 10 \%$

of the laboratory reference values for glucose concentrations $< 5.55 \text{ mmol/L}$ or $\geq 5.55 \text{ mmol/L}$, respectively, when tested via subject obtained capillary fingertip results (patients with diabetes)²



○ All samples (n = 600) — 0.6 mmol/L or 10% — 0.8 mmol/L or 15%

Interference Tolerance

Interferent (Substance)	Typical Reference Interval or Therapeutic Concentration Range ^{1,2}	Highest Test Concentration ³
Acetaminophen (Paracetamol)	0.066 – 0.199 mmol/L	2.19 mmol/L
Ascorbic acid (Ascorbate)	0.02 – 0.11 mmol/L*	0.69 mmol/L
Unconjugated Bilirubin	0.003 – 0.014 mmol/L	0.55 mmol/L
Cholesterol	< 5.2 mmol/L	36.0 mmol/L
Creatinine	For women 0.049 – 0.090 mmol/L For men 0.064 – 0.104 mmol/L (hydrochloride) 0.05 – 0.11 mmol/L*	(hydrochloride) 1.77 mmol/L
Dopamine	(hydrochloride) 0.002 mmol/L*	(hydrochloride) 0.40 mmol/L
EDTA		41.1 mmol/L
Galactose	0.3 mmol/L*	20.0 mmol/L
Gentisic Acid (Na Salt form: Sodium Gentisate)	0.01 – 0.04 mmol/L*	1.19 mmol/L
Glutathione	0.004 mmol/L	0.64 mmol/L
Hemoglobin	For women (11.7 – 16.1 g/dL) For men (12.6 – 17.4 g/dL)	0.19 mmol/L (1.2 g/dL)

*CLSI. Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition. EP7-A2. November 2005.

†Data on File. Ascensia Diabetes Care. Onyx Plus Icodextrin Interference Testing Report. June 5, 2015.

‡Lifescan Technical Bulletin 056-328-01, Interferences from Endogenous and Exogenous Substances (Mayo Laboratory, Rochester, MN)

§Wens R et al. *Perit Dial Int*. 1998 Nov-Dec;18(6):603-9.

1. CLSI. Interference Testing in Clinical Chemistry. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

2. CLSI. Supplemental Tables for Interference Testing in Clinical Chemistry. 1st ed. CLSI guideline EP37. PA: Clinical and Laboratory Standards Institute; 2018.

3. Data on File. Ascensia Diabetes Care. 30-September-2015 SATEPD-26374-2: Onyx-PLUS Interference testing report.

Interference Tolerance

Interferent (Substance)	Typical Reference Interval or Therapeutic Concentration Range ^{1, 2}	Highest Test Concentration ³
Heparin		10000 IU/dL
Ibuprofen	(Na salt) 0.05 – 0.34 mmol/L*	3.51 mmol/L
Icodextrin	0.3 mmol/L [†]	1.4 mmol/L [†]
L-Dopa (Levodopa)	0.001 – 0.0015 mmol/L [‡]	0.27 mmol/L
Maltose	3.3 mmol/L [§]	13.33 mmol/L
Methyldopa	0.004 – 0.031 mmol/L*	0.21 mmol/L
Pralidoxime Iodide (PAM)	0.1 mmol/L [†]	1.03 mmol/L
Sodium Salicylate	0.07 – 2.2 mmol/L*	Salicylate (Na salt) 8.13 mmol/L
Tolbutamide	0.1 mmol/L*	2.37 mmol/L
Tolazamide	0.2 – 0.4 mmol/L [‡]	2.60 mmol/L
Triglycerides	2.1 mmol/L [‡]	14.5 mmol/L

*CLSI. Interference Testing in Clinical Chemistry;

Approved Guideline – Second Edition. EP7-A2. November 2005.

[†]Data on File. Ascensia Diabetes Care. Onyx Plus Icodextrin Interference Testing Report. June 5, 2015.

[‡]Lifescan Technical Bulletin 056-328-01, Interferences from Endogenous and Exogenous Substances (Mayo Laboratory, Rochester, MN)

[§]Wens R et al. *Perit Dial Int.* 1998 Nov-Dec;18(6):603-9.

1. CLSI. Interference Testing in Clinical Chemistry. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

2. CLSI. Supplemental Tables for Interference Testing in Clinical Chemistry. 1st ed. CLSI guideline EP37. PA: Clinical and Laboratory Standards Institute; 2018.

3. Data on File. Ascensia Diabetes Care. 30-September-2015 SATEPD-26374-2: Onyx-PLUS Interference testing report.

Interference Tolerance

- Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

Interferent (Substance)	Typical Reference Interval or Therapeutic Concentration Range ^{1,2}	Highest Test Concentration ³
Uric acid (Urate)	For women 0.137 – 0.393 mmol/L For men 0.262 – 0.452 mmol/L 0.1 – 0.5 mmol/L*	2.65 mmol/L
Xylose	3.8 mmol/L†	0.77 mmol/L

*CLSI. Interference Testing in Clinical Chemistry;

Approved Guideline – Second Edition. EP7-A2. November 2005.

†Data on File. Ascensia Diabetes Care. Onyx Plus Icodextrin Interference Testing Report. June 5, 2015.

‡Lifescan Technical Bulletin 056-328-01, Interferences from Endogenous and Exogenous Substances (Mayo Laboratory, Rochester, MN)

§Wens R et al. *Perit Dial Int*. 1998 Nov-Dec;18(6):603-9.

1. CLSI. Interference Testing in Clinical Chemistry. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

2. CLSI. Supplemental Tables for Interference Testing in Clinical Chemistry. 1st ed. CLSI guideline EP37. PA: Clinical and Laboratory Standards Institute; 2018.

3. Data on File. Ascensia Diabetes Care. 30-September-2015 SATEPD-26374-2: Onyx-PLUS Interference testing report.

Meter Screen Display

Symbol	What the Symbol Means
	Fasting marker
	Before Meal marker
	After Meal marker
	No marker selected
	Meter is ready to test
	Add more blood to same test strip
	Control solution test result
	Bluetooth symbol: indicates the Bluetooth wireless setting is On; the meter can communicate with a mobile device

Symbol	What the Symbol Means
	Indicates low batteries
	Indicates dead batteries
	Indicates a meter error
	Reminder feature
	Sound feature
	7-, 14-, 30-, and 90-day averages
	Total number of blood glucose readings used to calculate averages

Error Detection Displays

- The meter screen displays error codes (E plus a number) for test result errors, strip errors, or system errors.
- Please contact Sales Representatives or Customer Service if you experience continued errors.

Error Code	What It Means	What to Do
Strip Errors		
E 1	Too Little Blood	Remove the strip. Repeat the test with a new strip.
E 2	Used Test Strip	Remove the strip. Repeat the test with a new strip.
E 3	Strip Upside Down	Remove the strip and insert it correctly.
E 4	Wrong Strip Inserted	Remove the strip. Repeat the test with a CONTOUR PLUS test strip.
E 6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.
E 8	Strip or Test Errors	Repeat the test with a new strip. If the error persists, contact Customer Service.

Error Code	What It Means	What to Do
Testing Errors		
E20	Testing Error	Repeat the test with a new strip. If the error persists, contact Customer Service.
E24	Too Cold to Test Control Solution	Move the meter, strip, and control solution to a warmer area. Test in 20 minutes.
E25	Too Hot to Test Control Solution	Move the meter, strip, and control solution to a cooler area. Test in 20 minutes.
E27	Too Cold to Test	Move the meter and strip to a warmer area. Test in 20 minutes.
E28	Too Hot to Test	Move the meter and strip to a cooler area. Test in 20 minutes.
System Errors		
E30–E99	Meter software or hardware malfunctioned	Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.

Thank you



Comparison Chart



	Feature	CONTOUR®PLUS ELITE ¹	CONTOUR®PLUS ²
Accuracy	ISO Standard	Exceeds ISO 15197:2013	Exceeds ISO 15197:2013
	Results within ± 0.83 mmol/L or 15%* *Number of results within ± 0.83 mmol/L when BG is < 5.6 mmol/L or $\pm 15\%$ when 5.6mmol/L	± 0.83 mmol/L or 15mg/dL 600/600 100%	± 0.83 mmol/L or 15mg/dL 600/600 100%
	Results within ± 0.56 mmol/L or 10%** **Number of results within ± 0.56 mmol/L when BG is < 5.6 mmol/L or $\pm 15\%$ when 5.6mmol/L	± 0.56 mmol/L or 10mg/dL 599/600 99.8%	± 0.56 mmol/L or 10mg/dL 598/600 99.7%
	User performance (fingertip capillary) vs YSI reference method	8.4% ³	10% ⁴
Easy of use	Display target range with colour indicator?	smartLIGHT™ coloured target range indicator	No colour indicator
	Colours: green, red & amber	GREEN, RED, AMBER	
	Ready to use out of the box?	YES	YES
Adapted to patients needs	Does it help reduce strip wastage, and prevent a second finger prick?	YES, 60 sec Second-Chance® sampling with countdown screen	YES, 30 sec Second-Chance® sampling
	Colour coded target range indicator	smartLIGHT™	NO
	Can the target ranges be changed on the meter?	YES	YES

Comparison Chart



	Features	CONTOUR®PLUS ELITE ¹	CONTOUR®PLUS ²
Adapted to patients needs	Meal markers	YES	YES
	Backlight screen	NO	NO
	Colour coded target range indicator	smartLIGHT™	NO
	Strip port light	YES	NO
	Test reminders	YES	YES
Practical	Type of blood glucose sample	C, V, A, N†	C, V, A, N†
	Enzyme	GDH-FAD	GDH-FAD
	Mesurement range	0.6 mmol/L to 33.3 mmol/L	0.6 mmol/L to 33.3 mmol/L
	Memory	800	480
	Averages	Yes, 7, 14, 30, 90 days	Yes, 7, 14, 30 days
	Hematocrit range	0-70%	0-70%
	Humidity range	10-93%	10-93%
	Meter operating temperature range	5-45°C	5-45°C
	Test time	5 sec countdown	5 sec countdown