

VivaChek™ Ino

Blood Glucose Monitoring System



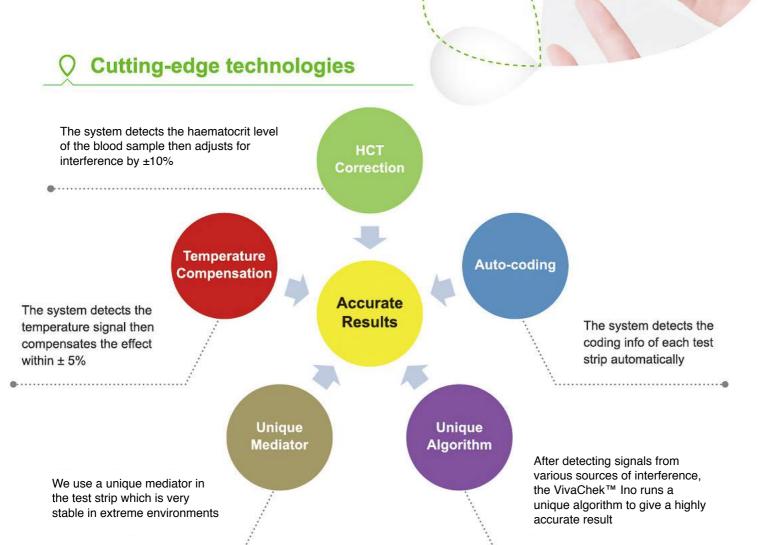
Fulfills all the requirements of DIN EN ISO 15197: 2013











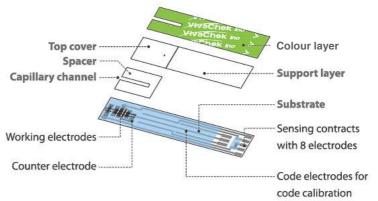
Advanced 8 electrodes

The 8 electrodes on the VivaChek $^{\text{TM}}$ Ino test strip work with the VivaChek $^{\text{TM}}$ Ino meter to deliver highly accurate results.

Detailed functions of the electrodes are:

......

- · No coding calibration
- Eliminating haematocrit interference
- · Eliminating temperature interference
- Checking for exposure to humidity
- Checking that sufficient sample has been added
- · Checking if the sample is control solution or blood
- · Checking if the test strip is damaged



Superior performance | Advanced features



8 electrodes



No coding



Can test neonates, pregnant women and anaemic patients



Wide operating temperature



0.5 µL blood sample



5s testing time



Insufficient sample detection



Strip ejector



900-test memory



Meal markers



Hypo warming



5 test alarms

Specification

Feature

Specification

Measurement range

0.6 to 33.3 mmol/L

Result calibration

Plasma-equivalent

Sample

Fresh capillary whole blood

Sample volume

About 0.5 µL

Test time

About 5 seconds

Power source

Two (2) CR 2032 3.0V coin cell batteries

Battery life

12 months or approximately 1,000 tests

Memory

900 records with date and time

Automatic shutoff

2 minutes after last action

Weight

Approximately 47g (with batteries)

Operating temperature

5-45 °C

Operating relative humidity

10-90% (non-condensing)

Haematocrit range

20-70%

Data port

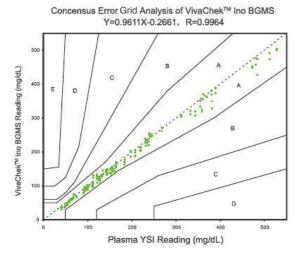
Micro USB

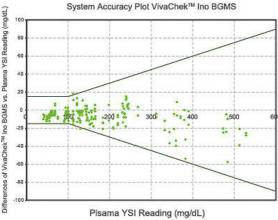




O Proven accuracy

A recent independent clinical study conducted by IDK Germany* shows that 98.8% of all results from VivaChek™ Ino blood glucose monitoring system are within ±15% or 15 mg/dL (0.83 mmol/L) of the YSI plasma results, which is fully compliant with the new DIN EN ISO 15197:2013 standard.





*IDK: Institute of Diabetes » Gerhardt Katsch « Karlsburg (www.diabetes-karlsburg.de).

Risk level (CEG zone)	Risk to diabetic patient
Α	No effect on clinic action
В	Altered clinical action-little or no effect on clinical outcome
С	Altered clinical action-likely to effect clinical outcome
D	Altered clinical action-could have significant medical risk
E	Altered clinical action-could have dangerous consequences

System accuracy results for glucose concentration
< 5.55 mmol/L (100 mg/dL)

Within ± 0.28 mmol/L (5 mg/dL)	78/186 (41.9%)
Within ± 0.56 mmol/L (10 mg/dL)	148/186 (79.6%)
Within ± 0.83 mmol/L (15 mg/dL)	185/186 (99.5%)

System accuracy results for glucose concentration ≥ 5.55 mmol/L (100 mg/dL)

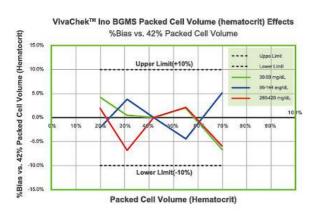
Within ± 5%	233/414 (56.3%)	
Within ± 10%	360/414 (87.0%)	
Within ± 15%	408/414 (98.6%)	

System accuracy results for glucose concentration between 2.28 mmol/L (40.9 mg/dL) and 29.4 mmol/L (528.3 mg/dL)

593/600 (98.8%)

O

Haematocrit effect study



Over and under estimation of glucose levels due to the haematocrit effect is a common source of error with many meter systems. Anaemia falsely elevates whilst polycythemia and dehydration falsely depresses blood glucose readings. The magnitude of this effect may vary 4 to 30% for every 10% change in the haematocrit, depending on the meter system. 1,2,3 According to the WHO, anaemia affects around 25% of the population, 47% of pre-school children and 42% of pregnant women worldwide. 4

With advanced haematocrit correction technology, the VivaChek™ Ino blood glucose monitoring system can be used for testing patients with a haematocrit level between 20 and 70%, including neonates with very high haematocrit levels as well as anaemic patients and pregnant women with very low haematocrit levels.

References

- 1. Consensus Statement on Self Monitoring of Blood Glucose. Diabetes Care 19
- 2. The effect of Haematocrit on reagent strip test for glucose. Diabet Med 1991;
- 3. Factors Affecting Blood Glucose Monitoring: Source of Errors in Measurement H.Gnsberg Barry, MD, Ph.DJ Diabetes Sci Technol, Jul 2009; 3 (4): 903-913,
- 4. Worldwide prevalence of anemia 1993-2005, WHO Global Database on Anaemia Geneva, World Health Organization, 2008.



Catalogue numbers | Ordering Information

tem	Catalogue No.	Contents
	VGM01-011	Meter 10 Test strips
ivaChek™ Ino Starter Kit		10 Lancets
		Lancing device
<u>esta e de trasa la re</u>		Control solution N (2mL)
	VGM01-012	Meter
VivaChek™ Ino Starter Kit II		10 Test strips
		10 Lancets
		Lancing device
		Meter
VivaChek™ Ino Meter Only Kit	VGM01-013	10 Lancets
		Lancing device
		Control solution N (2mL)
VivaChek™ Ino Meter Only Kit II	VGM01-014	Meter
		Lancing device
vivaChek™ Ino Meter Only Kit III	VGM01-015	Meter
	VGM01-016	Meter
VivaChek™ Ino Meter Only Kit IV		Lancing device
		10 Lancets
/ivaChek™ Ino Test Strips 50s (25/vial)	VGS01-011	50 Test strips (25/vial)
/ivaChek™ Ino Test Strips 25s (25/vial)	VGS01-012	25 Test strips (25/vial)
vivaChek™ Ino Test Strips 10s (10/vial)	VGS01-013	10 Test strips (10/vial)
/ivaChek™ Ino Test Strips 100s (25/vial)	VGS01-014	100 Test strips (25/vial)
VivaChek™ Ino Test Strips 50s (individual)	VGS01-015	50 Test strips (individual)
/ivaChek™ Ino Test Strips 25s (individual)	VGS01-016	25 Test strips (individual)
/ivaChek™ Ino Test Strips 100s (individual)	VGS01-017	100 Test strips (individual)
/ivaChek™ Ino Test Strips 50s (50/vial)	VGS01-018	50 Test Strips (50/vial)
/ivaChek™ Ino Test Strips 200s (50/vial)	VGS01-019	200 Test strips (50/vial)
/ivaChek™ Ino Test Strips 100s (50/vial)	VGS01-01A	100 Test strips (50/vial)
	VGC01-011	Control solution L (2mL)
VivaChek™ Ino Control Solution		Control solution N (2mL)
C. Law	VCD01 001	Control solution H (2mL)
/ivaChek™ Lancing Device	VGD01-001	Lancing device
/ivaChek™ Lancets 50s	VGL01-002	50 Lancets
/ivaChek™ Encets 100s	VGL01-003	100 Lancets
/ivaChek™ Safety Lancets 50s /ivaChek™ Safety Lancets 100s	VGL02-001 VGL02-002	50 Safety lancets 100 Safety lancets





Distributed in the United Kingdom by;

JRBiomedical Ltd.
Glyndŵr University OpTIC Centre
St Asaph Business Park
St Asaph
LL17 0JD
United Kingdom

Freephone 0800 612 7531 help@jrbiomedical.com

Version JRB130617

© JRBiomedical Ltd 2017