Country-Specific Glucose Monitor List

Country Name: South Africa

New Important Information

The glucose monitors manufacturers listed have certified to Baxter that they have tested (as per 2013 ISO 15197) their monitors with maltose and icodextrin to Baxter's recommended limits: 278 mg/dL (maltose) and 1094 mg/dL (icodextrin). The manufacturers certified that their "green" monitors, below, showed no interference of blood glucose readings under these conditions.

Important Information

This list is compiled from a search via: Internet, literature, Baxter internal studies, information from government agencies, test strip leaflets, safety alerts, and direct information from the product manufacturers. While efforts have been made to provide accurate and current information, Baxter does not manufacture these glucose monitors or test strips and thus does not guarantee the initial or continued accuracy of this information. Please contact the manufacturer(s) of the glucose monitor and test strip to obtain the latest compatibility information before using in conjunction with EXTRANEAL (Icodextrin) peritoneal dialysis (PD) solution.

- 1. EXTRANEAL (Icodextrin) PD solution contains icodextrin. Maltose, a metabolite of icodextrin, may interfere with certain glucose monitors or test strips. This interference will result in a falsely elevated glucose reading using these monitors or test strips.
- 2. This interference may mask true hypoglycemia or lead to the erroneous diagnosis of hyperglycemia. Thus, a blood glucose reading within or above the normal range in a patient on EXTRANEAL (Icodextrin) PD solution, using these monitors or test strips, may mask true low blood sugar. This would cause a patient or health care professional to not take the appropriate steps to bring the blood sugar into a normal range. Or, a falsely-elevated blood glucose reading could cause a patient to get more insulin than needed. Both of these situations can lead to life-threatening events, including loss of consciousness, coma, neurological damage or death.
- 3. The dialysis unit or patient should contact the manufacturer of the glucose monitor and/or test strips to determine if the monitor or test strips they are using are subject to interference by icodextrin or maltose. Also, consult the product information included with the glucose monitor and test strips.
- 4. The following list is for reference only. This list does not imply recommendation of these glucose monitors or test strips.
- 5. Identified compatibilities are shown in the table below. <u>ONLY</u> glucose-specific monitors and test strips should be used with patients on EXTRANEAL (Icodextrin) PD solution. Contact the manufacturer to verify that the test strips and monitor are glucose-specific. The list provides the contact information of the more common, major brand manufacturers.
- 6. This is a non-comprehensive list, current as of November 2014. Absence of your specific glucose monitor or test strips from this list does <u>NOT</u> imply compatibility with EXTRANEAL (Icodextrin) PD solution. Always contact the manufacturer for current information. Baxter has no obligation to update the content of this list.

GLUCOSE MONITORS November 2014

Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer
Boots	Yes	GDH-NAD	
FreeStyle InsuLinx	Yes	GDH-FAD	Abbott Diabetes Care
FreeStyle Optium	Yes	GDH-NAD	www.abbottdiabetescare.com
FreeStyle Optium H	Yes	GDH-NAD	
FreeStyle Optium Neo	Yes	GDH-NAD	Phone: 0800-222-688
FreeStyle Papillon InsuLinx	Yes	GDH-FAD	
FreeStyle Precision	Yes	GDH-NAD	
FreeStyle Precision H	Yes	GDH-NAD	
FreeStyle Precision Neo	Yes	GDH-NAD	
FreeStyle Precision Pro	Yes	GDH-NAD	
Omron HEA-214	Yes	GDH-NAD	
Optium	Yes	GDH-NAD	

Glucose Monitor Brand	Compatible with Extraneal	Test Type*	Manufacturer
	(Icodextrin) PD solution		
	(Glucose-specific)		
Optium Easy	Yes	GDH-NAD	
OptiumEZ	Yes	GDH-NAD	
Optium Xceed	Yes	GDH-NAD	
Optium Xido	Yes	GDH-NAD	
Precision PCx ¹	Yes ¹	GDH-NAD, GO ¹	
Precision QID ^B	Yes	GO	
Precision Xceed	Yes	GDH-NAD	
Precision Xceed Pro	Yes	GDH-NAD	
Precision Xtra	Yes	GDH-NAD	
Precision Xtra OK ¹	Yes ¹	GDH-NAD, GO ¹	
ReliOn Ultima	Yes	GDH-NAD	
TrueSense	Yes	GDH-NAD	
FreeStyle Flash ²	Yes ²	GDH-FAD ²	
FreeStyle Flash ²	No ²	GDH-PQQ ²	
FreeStyle Freedom ²	Yes ²	GDH-FAD ²	
FreeStyle Freedom ²	No ²	GDH-PQQ ²	
FreeStyle Freedom Lite ²	Yes ²	GDH-FAD ²	
FreeStyle Freedom Lite ²	No ²	GDH-PQQ ²	
FreeStyle Lite ²	Yes ²	GDH-FQQ GDH-FAD ²	
FreeStyle Lite ²	No ²	GDH-PQQ ²	
FreeStyle Mini ²	Yes ²	GDH-FQQ GDH-FAD ²	
FreeStyle Mini ²	No ²	GDH-PQQ ²	
FreeStyle Papillon Lite ²	Yes ²	GDH-FQQ GDH-FAD ²	
	Yes No ²		
FreeStyle Papillon Lite ²	Yes ²	$\mathbf{GDH} - \mathbf{PQQ}^2$	
FreeStyle Papillon Mini ²	Yes No ²	GDH-FAD ²	
FreeStyle Papillon Mini ²	No Yes ²	$GDH-PQQ^2$	
FreeStyle Papillon Vision ²	Yes No ²	GDH-FAD ²	
FreeStyle Papillon Vision ²		GDH-PQQ ²	
Advance Intuition	Yes	GO	
Assure Platinum	Yes	GO	Arkray, Inc.
Assure Pro	Yes	GO	www.arkrayusa.com
Assure 4	Yes	GO	
GLUCOCARD 01	Yes	GO	
GLUCOCARD 01-mini	Yes	GO	
GLUCOCARD 01-mini plus	Yes	GO	
GLUCOCARD Expression	Yes	GO	
GLUCOCARD MyDIA	Yes	GO	
GLUCOCARD Vital	Yes	GO	
GLUCOCARD Σ	Yes	GO	
GLUCOCARD Σ-mini	Yes	GO	
PocketChem EZ	Yes	GO	
ReliOn Confirm	Yes	GO	
ReliOn micro	Yes	GO	
ReliOn Prime	Yes	GO	
GLUCOCARD X-meter ^{D,3}	No ³	GDH-FAD ³	
GLUCOCARD X-mini ³	No ³	GDH-FAD ³	
GLUCOCARD X-mini plus ³	No ³	GDH-FAD³	

Glucose Monitor Brand	Compatible with Extraneal	Test Type*	Manufacturer
	(Icodextrin) PD solution		
	(Glucose-specific)	~~~	
Ascensia Brio	Yes	GO	
Ascensia Entrust	Yes	GO	Bayer Healthcare
Breeze 2	Yes	GO	www.bayerdiabetes.com
Contour	Yes	GDH-FAD	DI (011) 021 5055
Contour Link Contour Next	Yes Yes	GDH-FAD	Phone: (011) 921 5055 Help Desk: 0860 102 672
Contour Next EZ	Yes	GDH-FAD GDH-FAD	Help Desk: 0800 102 672
Contour Next EZ	Yes	GDH-FAD GDH-FAD	
Contour Next USB	Yes	GDH-FAD GDH-FAD	
Contour Plus	Yes	GDH-FAD	
Contour TS	Yes	GDH-FAD	
Contour USB	Yes	GDH-FAD	
Contour XT	Yes	GDH-FAD GDH-FAD	
Didget	Yes	GDH-FAD	
Elite	Yes	GO	
Elite XL	Yes	GO	
OneTouch InDuo	Yes	GO	
OneTouch Ping	Yes	GO	LifeScan South Africa
OneTouch Select	Yes	GO	www.lifescan.com
OneTouch Select Mini	Yes	GO	
OneTouch Select Simple	Yes	GO	Phone:
OneTouch SureStep	Yes	GO	+27 011 518 7000
OneTouch Ultra ^E	Yes	GO	+27 011 518 7000
OneTouch Ultra 2	Yes	GO	
OneTouch UltraEasy	Yes	GO	
OneTouch UltraLink	Yes	GO	
OneTouch UltraMini	Yes	GO	
OneTouch UltraSmart	Yes	GO	
OneTouch UltraVue	Yes	GO	
OneTouch Verio	Yes	GDH-FAD	
OneTouch VerioPro	Yes	GDH-FAD	
OneTouch VerioPro+	Yes	GDH-FAD	
OneTouch VerioSync	Yes	GDH-FAD	
OneTouch Vita	Yes	GO	
SureStep Flexx	Yes	GO	
Accu-Chek Nano ⁵	Yes ⁵	Mut Q-GDH ⁵	
Accu-Chek Nano SmartView ⁵	Yes ⁵	Mut Q-GDH ⁵	Roche Diagnostics
Accu-Chek Mobile	Yes	Mut Q-GDH	www.roche-diagnostics.com
Accu-Chek Inform II	Yes	Mut Q-GDH	www.accu-chek.com
Accu-Chek Aviva Plus ⁵	Yes ⁵	Mut-Q-GDH ⁵	
A corr Chalt A -ti4	Yes ⁴	Mat O CDIT ⁴	Phone: 080-34-22-38-37
Accu-Chek Active ⁴	Yes ¹ No ⁴	Mut-Q-GDH ⁴	
Accu-Chek Active/S System ⁴ Accu-Chek Aviva ⁴	No ⁺ Yes ⁴	GDH-PQQ⁴ Mut-Q-GDH ⁴	
Accu-Chek Aviva ⁴	Yes No ⁴	GDH-PQQ ⁴	
Accu-Chek Aviva Accu-Chek Aviva Combo ⁴	INO Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Aviva Combo ⁴	No ⁴	GDH-PQQ ⁴	
Accu-Chek Aviva Combo Accu-Chek Aviva Expert ⁴	INO Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Aviva Expert ⁴	No ⁴	GDH-PQQ ⁴	
Accu-Chek Aviva Expert	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Aviva Nano ⁴	No ⁴	GDH-PQQ ⁴	
Accu-Chek Compact Plus ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Compact Plus ^{A,4}	No ⁴	GDH-PQQ ⁴	
Accu-Chek Performa ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Performa ⁴	No ⁴	GDH-PQQ ⁴	
Accu-Chek Performa Combo ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Performa Combo ⁴	No ⁴	GDH-PQQ ⁴	

Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer
Accu-Chek Performa Nano ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Performa Nano ⁴	No ⁴	GDH-PQQ ⁴	
Accu-Chek Advantage ^A	No	GDH-PQQ	
Accu-Chek Comfort	No	GDH-PQQ	
Accu-Chek Compact	No	GDH-PQQ	
Accu-Chek Complete System	No	GDH-PQQ	
Accu-Chek Go/Go S System	No	GDH-PQQ	
Accu-Chek GTS/GTS Plus	No	GDH-PQQ	
Accu-Chek Inform System	No	GDH-PQQ	
Accu-Chek Inform	No	GDH-PQQ	
Accu-Chek Integra System	No	GDH-PQQ	
Accu-Chek Plus	No	GDH-PQQ	
Accu-Chek Sensor	No	GDH-PQQ	
Accu-Chek Voicemate/Voice	No	GDH-PQQ	
Mate Plus System			

¹ Two types of **compatible** test strips for Precision PCx and Precision Xtra OK.

² These brand name monitors can utilize either GDH-PQQ (incompatible) or GDH-FAD (compatible) strips. Consult manufacturer for additional information.

³ These Arkray GDH-FAD monitors/test strip are **incompatible**. <u>Consult manufacturer for additional information</u>.

 ⁴ These brand name monitors can utilize either GDH-PQQ (incompatible) or Mut Q-GDH (compatible) strips. Consult manufacturer for additional information.
⁵ The ACCU-CHEK Nano (not Aviva or Performa) and ACCU-CHEK Aviva Plus glucose systems are available

⁵ The ACCU-CHEK Nano (<u>not Aviva or Performa</u>) and ACCU-CHEK Aviva Plus glucose systems are available within the United States ONLY, and use test strips branded as ACCU-CHEK Smartview and ACCU-CHEK Aviva Plus, respectively. These systems use the MUT Q-GDH (**compatible**) strips. <u>Consult manufacturer for additional information</u>.

Test Type*

 $\mathbf{GO} =$ glucose oxidase

GDH-PQQ = glucose dehydrogenase with pyrroloquinolinequinone (note: **GDO**, glucose-dye-oxidoreductase, is an **incompatible** PQQ-based method)

GDH-NAD = glucose dehydrogenase with nicotinamide-adenine dinucleotide

GDH-FAD = glucose dehydrogenase with flavin-adenine dinucleotide

Mut Q-GDH = glucose dehydrogenase with pyrroloquinolinequinone modified to eliminate maltose interference

References:

^A Baxter report 32386 Determination of potential interference of icodextrin and its metabolites on human blood glucose measurement using Accu-Chek compact and Advantage systems.

^B Baxter report REP-NIV-RE-366 Evaluation of potential interference in blood glucose determination (measured with enzymatic methods) for patients treated with icodextrin.

^c Baxter report RD-01-RE-233 Evaluation of potential interference in the blood glucose test kit MediSense Sof-Tact with icodextrin and its metabolites.

^{**D**} Baxter report Interim 3, 33541 Determination of potential interference of icodextrin and its metabolites on human blood glucose measurement using chosen glucometer, Glucocard X-Meter (Arkray).

^E Baxter report Interim 1, 33541 Determination of potential interference of icodextrin and its metabolites on human blood glucose measurement using chosen glucometers.

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