Country-Specific Glucose Monitor List

Country Name: Malta

Important Information

This is a non-comprehensive list, current as of Dec 2015. Absence of a specific glucose monitor or test strips from this list does NOT imply compatibility or incompatibility with EXTRANEAL (Icodextrin) PD solution. Similarly, other glucose-measuring technologies which are not listed below (such as continuous glucose monitoring systems) may or may not be compatible with EXTRANEAL. Always contact the device manufacturer for current information. If the manufacturer cannot provide information regarding compatibility of the device with icodextrin and maltose, Baxter does NOT recommend that Extraneal patients use the product. Baxter reserves the right to change this list without notice and does not represent that it includes all potentially incompatible products.

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, with the exception of the "green" monitors specifically notated for which certification of testing to Baxter's recommended limits has not yet been received.

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. ONLY 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.

GLUCOSE MONITORS

Updated Dec, 2015

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	Phone: +356 2145 4166
FreeStyle Optium Neo	Yes	GDH-NAD	
FreeStyle Optium Neo H	Yes	GDH-NAD	
FreeStyle Papillon InsuLinx	Yes	GDH-FAD	
FreeStyle Precision	Yes	GDH-NAD	
FreeStyle Precision H	Yes	GDH-NAD	
FreeStyle Precision Neo	Yes	GDH-NAD	

Glucose Monitor Brand	Compatible with Extraneal	Test Type*	Manufacturer
	(Icodextrin) PD solution		
	(Glucose-specific)		
FreeStyle Precision Pro	Yes	GDH-NAD	
Omron HEA-214	Yes	GDH-NAD	
Optium	Yes	GDH-NAD	
Optium Easy	Yes	GDH-NAD	
OptiumEZ	Yes	GDH-NAD	
Optium Xceed	Yes	GDH-NAD	
Optium Xido	Yes	GDH-NAD	
Optium Xido Neo	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-FAD ²	
FreeStyle Lite ²	No^2	GDH-PQQ ²	
FreeStyle Mini ²	Yes ²	GDH-FAD ²	
FreeStyle Mini ²	No^2	GDH-PQQ ²	
FreeStyle Papillon Lite ²	Yes ²	GDH-FAD ²	
FreeStyle Papillon Lite ²	No^2	GDH-PQQ ²	
FreeStyle Papillon Mini ²	Yes ²	GDH-FAD ²	
FreeStyle Papillon Mini ²	No^2	GDH-PQQ ²	
FreeStyle Papillon Vision ²	Yes ²	GDH-FAD ²	
FreeStyle Papillon Vision ²	No 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 G Black	Yes	GDH-FAD	
GLUCOCARD MyDIA	Yes	GO	
GLUCOCARD Prism ⁶	Yes ⁶	GO^6	
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 ^{C,3}	No ³	GDH-FAD ³	
GLUCOCARD X-mini ³	No^3	GDH-FAD ³	
GLUCOCARD X-mini plus ³	No^3	GDH-FAD ³	
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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	Phone: +356 2144 6133
Contour Link	Yes	GDH-FAD	+356 2144 6134
Contour Next	Yes	GDH-FAD	7000 2111 0101
Contour Next EZ	Yes	GDH-FAD	
Contour Next Link	Yes	GDH-FAD	
Contour Next Link 2.4	Yes	GDH-FAD	
Contour Next USB	Yes	GDH-FAD	
Contour Plus	Yes	GDH-FAD	
Contour Plus Link 2.4	Yes	GDH-FAD	
Contour TS	Yes	GDH-FAD	
Contour USB	Yes	GDH-FAD	
Contour XT	Yes	GDH-FAD	
Elite	Yes	GO	
Elite XL	Yes	GO	
OneTouch InDuo	Yes	GO	
OneTouch Ping	Yes	GO	Lifescan, Inc.
OneTouch Select	Yes	GO	www.lifescan.com
OneTouch Select Mini	Yes	GO	Phone: +356 2124 2017
OneTouch Select Simple	Yes	GO	
OneTouch SureStep	Yes	GO	
OneTouch Ultra ^D	Yes	GO	
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 VerioIQ	Yes	GDH-FAD	
OneTouch VerioPro	Yes	GDH-FAD	
OneTouch VerioPro+	Yes	GDH-FAD	
OneTouch VerioSync	Yes	GDH-FAD	
OneTouch VerioVue	Yes	GDH-FAD	
OneTouch Vita	Yes	GO	
SureStep Flexx	Yes	GO	
Accu-Chek Active	Yes	Mut Q-GDH	Roche Diagnostics
Accu-Chek Aviva Combo	Yes	Mut Q-GDH	www.accu-chek.com
Accu-Chek Aviva Connect	Yes	Mut Q-GDH	
Accu-Chek Aviva Expert	Yes	Mut Q-GDH	Phone: +356 2134 4610
Accu-Chek Aviva Insight	Yes	Mut Q-GDH	
Accu-Chek Aviva Nano	Yes	Mut Q-GDH	
Accu-Chek Aviva Plus ⁵	Yes ⁵	Mut-Q-GDH ⁵	
Accu-Chek Compact Plus	Yes	Mut Q-GDH	
Accu-Chek Inform II	Yes	Mut Q-GDH	
Accu-Chek Nano ⁵	Yes ⁵	Mut Q-GDH ⁵	
Accu-Chek Nano SmartView ⁵	Yes ⁵	Mut Q-GDH ⁵	
Accu-Chek Mobile	Yes	Mut Q-GDH	
Accu-Chek Performa	Yes	Mut Q-GDH	
Accu-Chek Performa Combo	Yes	Mut Q-GDH	
Accu-Chek Performa Connect	Yes	Mut Q-GDH	
Accu-Chek Performa Insight	Yes	Mut Q-GDH	
Accu-Chek Performa Nano	Yes	Mut Q-GDH	
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Accu-Chek Aviva	Yes ⁴	Mut-Q-GDH ⁴	
Accu-Chek Aviva ⁴	No ⁴	GDH-PQQ⁴	

Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer
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			
Nova Max Plus	Yes	GO	
Nova Max Link	Yes	GO	
StatStrip Hospital Glucose	Yes	GO	Nova Biomedical
Meter			
StatStrip Xpress Glucose	Yes	GO	
Meter			www.novabiomedical.com
Nova Pro Glucose/ Ketone Meter	Yes	GDH- FAD	

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

Test Type*

 $\overline{\mathbf{GO}} = \mathbf{glucose}$ 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:

Please see full prescribing information for EXTRANEAL (icodextrin) PD solution.

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

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

⁴ This brand name monitor can utilize either Mut Q-GDH (**compatible**) strips or GDH-PQQ (**incompatible**). The GDH-PQQ (**incompatible**) version is in the United States ONLY. Consult manufacturer for additional information.

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 (<u>compatible</u>) strips. Consult manufacturer for additional information.

⁶ This/These monitor/test strips were not currently certified as having been tested to Baxter's recommended interference limits for maltose or icodextrin when this List was issued. Consult manufacturer for additional information

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

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