Country Specific Glucose Monitor List

Country Name: USA

New Important Information

The glucose monitors manufacturers listed have certified to Baxter Healthcare Corporation 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 notated⁶ for which certification of testing to Baxter's recommended limits has not yet been received.

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.
- 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 June 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 Updated June 2014

Glucose Monitor Brand	Compatible with	Test Type*	Manufacturer
	EXTRANEAL (icodextrin) PD		
	solution (Glucose-specific)		
Boots	Yes	GDH-NAD	
FreeStyle InsuLinx	Yes	GDH-FAD	
FreeStyle Optium	Yes	GDH-NAD	
FreeStyle Optium H	Yes	GDH-NAD	
FreeStyle Optium Neo	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	
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	
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	Abbott Diabetes Care
Precision Xtra	Yes	GDH-NAD	www.abbottdiabetescare.com
Precision Xtra OK ¹	Yes ¹	GDH-NAD, GO ¹	Phone: 888-522-5226
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-FAD²	
FreeStyle Freedom ²	No ²	GDH-PQQ ²	
FreeStyle Freedom Lite ²	Yes ²	GDH-FAD²	
FreeStyle Freedom Lite ²	No ²	GDH-PQQ ²	
FreeStyle Lite ²	Yes ²	GDH-FAD²	
FreeStyle Lite ²	No ²	GDH-PQQ ²	
FreeStyle Mini ²	Yes ²	GDH-FAD²	
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	

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Advance Intuition	Yes	GO	
Assure Platinum	Yes	GO	
Assure Pro	Yes Yes	GO	
Assure 4		GO	
GLUCOCARD 01	Yes	GO	
GLUCOCARD 01-mini	Yes	GO	
GLUCOCARD 01-mini plus	Yes	GO	
GLUCOCARD Expression	Yes	GO	Arkray, Inc.
GLUCOCARD MyDIA	Yes	GO	www.arkrayusa.com
GLUCOCARD Vital	Yes	GO	Phone: 800-818-8877, Option
GLUCOCARD Σ	Yes	GO	#5
GLUCOCARD Σ-mini	Yes	GO	
PocketChem EZ	Yes	GO	
ReliOn Confirm	Yes	GO	
ReliOn micro	Yes	GO	
ReliOn Prime	Yes No ³	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-FAD ³	
Ascensia Brio	Yes	GO	
Ascensia Entrust	Yes	GO	
Breeze 2	Yes	GO	
Contour	Yes	GDH-FAD	
Contour Link	Yes	GDH-FAD	
Contour Next	Yes	GDH-FAD	
Contour Next EZ	Yes	GDH-FAD	
Contour Next Link	Yes	GDH-FAD	Bayer Healthcare
Contour Next USB	Yes	GDH-FAD	www.bayerdiabetes.com
Contour Plus	Yes	GDH-FAD	Phone: 800-348-8100
Contour TS	Yes	GDH-FAD	
Contour USB	Yes	GDH-FAD	
Contour XT	Yes	GDH-FAD	
Didget	Yes	GDH-FAD	
Elite	Yes	GO	
Elite XL	Yes	GO	
OneTouch InDuo	Yes	GO	
OneTouch Ping	Yes	GO	
OneTouch Select	Yes	GO	
OneTouch Select Mini	Yes	GO	
OneTouch Select Simple	Yes	GO	
OneTouch SureStep	Yes	GO	
OneTouch Ultra ^E	Yes	GO	
OneTouch Ultra 2	Yes	GO	Lifescan, Inc.
OneTouch UltraEasy	Yes	GO GO	www.lifescan.com
OneTouch UltraLink	Yes	GO GO	Phone: 800-524-SCAN
OneTouch UltraMini	Yes	GO GO	800-227-8862
OneTouch UltraSmart	Yes	GO GO	000-227-0002
OneTouch UltraVue		GO GO	
	Yes		
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	1

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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	Roche Diagnostics
Accu-Chek Inform II	Yes	Mut Q-GDH	www.roche-diagnostics.com
Accu-Chek Aviva Plus ⁵	Yes ⁵	Mut Q-GDH ⁵	<u>www.accu-chek.com</u> 800-858-8072
Accu-Chek Active ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Active/S System ⁴	No ⁴	GDH-PQQ⁴	
Accu-Chek Aviva ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Aviva ⁴	No ⁴	GDH-PQQ⁴	
Accu-Chek Aviva Combo ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Aviva Combo ⁴	No ⁴	GDH-PQQ ⁴	
Accu-Chek Aviva Expert ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Aviva Expert ⁴	No ⁴	GDH-PQQ ⁴	
Accu-Chek Aviva Nano ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Aviva Nano ⁴	No ⁴	GDH-PQQ⁴	
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-PQQ⁴	
Accu-Chek Performa Combo ⁴	Yes ⁴	Mut Q-GDH ⁴	
Accu-Chek Performa Combo ⁴	No ⁴	GDH-PQQ⁴	
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			
Nova Max Plus	Yes	GO	NovaBiomedical
Nova Max Link	Yes	GO	www.novabiomedical.com
StatStrip Hospital	Yes	GO	800-458-5813
StatStrip Xpress	Yes	GO	781-894-0800
'D CS4-6	V 6		
iBGStar ⁶	Yes ⁶	GO ⁶	
Liberty ⁶	Yes ⁶	GO ⁶	AgaMatrix, Inc. www.agamatrix.com
Liberty II	No	GDH-PQQ	866-906-4197

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. <u>Consult</u> <u>manufacturer for additional information.</u>

 ³ These Arkray GDH-FAD monitors/test strips 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 (but not ACCU-CHEK <u>Aviva or ACCU-CHEK Performa</u>) and ACCU-CHEK Aviva Plus glucose systems are available within the United States ONLY, and use test strips which are branded as ACCU-CHEK **Smartview** and ACCU-CHEK **Aviva Plus**, respectively. These systems use the MUT Q-GDH (**compatible**) chemistry. <u>Consult manufacturer for additional information</u>.

⁶ These monitors/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. These monitors have previously been certified as compatible by the manufacturer based on the test type. <u>Consult manufacturer(s) for additional information</u>.

Test Type*

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:

^ABaxter 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.

^{**b**} 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.

Indication and Important Risk Information for EXTRANEAL (icodextrin) Peritoneal Dialysis Solution

Indication:

Extraneal (icodextrin) Peritoneal Dialysis Solution is indicated for a single daily exchange for the long (8- to 16hour) dwell during continuous ambulatory peritoneal dialysis (CAPD) or automated peritoneal dialysis (APD) for the management of end-stage renal disease. EXTRANEAL is also indicated to improve (compared to 4.25% dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in patients with high average or greater transport characteristics, as defined using the peritoneal equilibration test (PET).

Important Risk Information:

Dangerous Drug-Device Interaction

Only use glucose-specific monitors and test strips to measure blood glucose levels in patients using **Extraneal** (icodextrin) Peritoneal Dialysis Solution. Blood glucose monitoring devices using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used. In addition, some blood glucose monitoring systems using glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD)-based methods must not be used. Use of GDH-PQQ, GDO, and GDH-FAD-based glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose, see **PRECAUTIONS/Drug/Laboratory Test Interactions**). Falsely elevated glucose readings have led patients or health care providers to withhold treatment of hypoglycemia or to administer insulin inappropriately. Both of these situations have resulted in unrecognized hypoglycemia, which has led to loss of consciousness, coma, permanent neurological damage, and death. Plasma levels of **Extraneal** (icodextrin) and its metabolites return to baseline within approximately 14 days following cessation of **Extraneal** (icodextrin) administration. Therefore falsely elevated glucose levels may be measured up to two weeks following cessation of **Extraneal** (icodextrin) therapy when GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors and test strips are used.

Because GDH-PQQ, GDO, and GDH-FAD-based blood glucose monitors may be used in hospital settings, it is important that the health care providers of peritoneal dialysis patients using **Extraneal** (icodextrin) carefully review the product information of the blood glucose testing system, including that of test strips, to determine if the system is appropriate for use with **Extraneal** (icodextrin).

To avoid improper insulin administration, educate patients to alert health care providers of this interaction whenever they are admitted to the hospital.

The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose readings. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP or visit www.glucosesafety.com.

Extraneal (icodextrin) is contraindicated in patients with a known allergy to cornstarch or icodextrin, in patients with maltose or isomaltose intolerance, in patients with glycogen storage disease, and in patients with pre-existing severe lactic acidosis

Extraneal PD solution is intended for intraperitoneal administration only. Not for intravenous injection

Rarely, serious hypersensitivity reactions to **Extraneal** have been reported, such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and leukocytoclastic vasculitis. If a serious reaction is suspected, discontinue **Extraneal** and institute appropriate treatment as clinically indicated

Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment

A patient's volume status should be carefully monitored to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion and hypovolemic shock. An accurate fluid balance record must be kept and the patient's body weight monitored

In clinical trials, the most frequently reported adverse events occurring in $\geq 10\%$ of patients, and more common in **Extraneal** (icodextrin) PD solution patients than in control patients, were peritonitis, upper respiratory infection, hypertension, and rash. The most common treatment-related adverse event for **Extraneal** PD solution patients was skin rash. Additional adverse reactions have been reported in the post-marketing setting and are detailed in the full prescribing information

General Peritoneal Dialysis-Related

Encapsulating peritoneal sclerosis (EPS) is a known, rare complication of peritoneal dialysis therapy. EPS has been reported in patients using peritoneal dialysis solutions including **Extraneal** PD solution. Infrequent but fatal outcomes have been reported

Aseptic technique should be used throughout the peritoneal dialysis procedure to reduce the possibility of infection, such as peritonitis

Fluid status, hematologic indices, blood chemistry, and electrolyte concentrations, including calcium, potassium, sodium, magnesium and bicarbonate, should be monitored periodically. Abnormalities in any of these parameters should be treated promptly under the care of a physician

Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Treatment of overinfusion is to drain the peritoneal dialysis solution from the peritoneal cavity

Treatment should be initiated and monitored under the supervision of a physician knowledgeable in the management of patients with renal failure

Please see Indication and Important Risk Information for EXTRANEAL (icodextrin) PD Solution, including BOXED WARNING on pages 6-7. Please see the full <u>Prescribing Information</u> and <u>Medication Guide</u>.

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