

Country-Specific Glucose Monitor List

Country Name: USA

Important Information

This is a non-comprehensive list, current as of March 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 notated⁶ 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 March, 2015

Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer
Boots FreeStyle InsuLinx FreeStyle Optium FreeStyle Optium H	Yes Yes Yes Yes	GDH-NAD GDH-FAD GDH-NAD GDH-NAD	Abbott Diabetes Care www.abbottdiabetescare.com Phone: 888-522-5226

Please see Indication and Important Risk Information for EXTRANEAL (icodextrin) PD Solution, including BOXED WARNING on pages 5-6. Please see the full [Prescribing Information](#) and [Medication Guide](#).

Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer
FreeStyle Optium Neo FreeStyle Optium Neo H FreeStyle Papillon InsuLinX FreeStyle Precision FreeStyle Precision H FreeStyle Precision Neo FreeStyle Precision Pro Omron HEA-214 Optium Optium Easy OptiumEZ Optium Xceed Optium Xido Optium Xido Neo Precision PCx ¹ Precision QID ^B Precision Xceed Precision Xceed Pro Precision Xtra Precision Xtra OK ¹ ReliOn Ultima TrueSense	Yes Yes	GDH-NAD GDH-NAD GDH-FAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD GDH-NAD, GO ¹ GO GDH-NAD GDH-NAD GDH-NAD GDH-NAD, GO ¹ GDH-NAD GDH-NAD	
FreeStyle Flash ² FreeStyle Flash ² FreeStyle Freedom ² FreeStyle Freedom ² FreeStyle Freedom Lite ² FreeStyle Freedom Lite ² FreeStyle Lite ² FreeStyle Lite ² FreeStyle Mini ² FreeStyle Mini ² FreeStyle Papillon Lite ² FreeStyle Papillon Lite ² FreeStyle Papillon Mini ² FreeStyle Papillon Mini ² FreeStyle Papillon Vision ² FreeStyle Papillon Vision ²	Yes ² No ² Yes ² No ² Yes ² No ² Yes ² No ² Yes ² No ² Yes ² No ² Yes ² No ² Yes ² No ²	GDH-FAD ² GDH-PQQ ² GDH-FAD ² GDH-PQQ ² GDH-FAD ² GDH-PQQ ² GDH-FAD ² GDH-PQQ ² GDH-FAD ² GDH-PQQ ² GDH-FAD ² GDH-PQQ ² GDH-FAD ² GDH-PQQ ²	
Advance Intuition Assure Platinum Assure Pro Assure 4 GLUCOCARD 01 GLUCOCARD 01-mini GLUCOCARD 01-mini plus GLUCOCARD Expression GLUCOCARD G Black GLUCOCARD MyDIA GLUCOCARD Prism ⁶ GLUCOCARD Vital GLUCOCARD Σ	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes ⁶ Yes Yes	GO GO GO GO GO GO GO GDH-FAD GO GO ⁶ GO GO	Arkray, Inc. www.arkrayusa.com Phone: 800-818-8877

Please see Indication and Important Risk Information for EXTRANEAL (icodextrin) PD Solution, including BOXED WARNING on pages 5-6. Please see the full [Prescribing Information](#) and [Medication Guide](#).

Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer
GLUCOCARD Σ-mini PocketChem EZ ReliOn Confirm ReliOn micro ReliOn Prime GLUCOCARD X-meter ^{C,3} GLUCOCARD X-mini ³ GLUCOCARD X-mini plus ³	Yes Yes Yes Yes Yes No ³ No ³ No ³	GO GO GO GO GO GDH-FAD ³ GDH-FAD ³ GDH-FAD ³	
Ascensia Brio Ascensia Entrust Breeze 2 Contour Contour Link Contour Next Contour Next EZ Contour Next Link Contour Next Link 2.4 Contour Next USB Contour Plus Contour Plus Link 2.4 Contour TS Contour USB Contour XT Elite Elite XL	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	GO GO GO GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GO GO	Bayer Healthcare www.bayerdiabetes.com Phone: 800-348-8100
OneTouch InDuo OneTouch Ping OneTouch Select OneTouch Select Mini OneTouch Select Simple OneTouch SureStep OneTouch Ultra ^D OneTouch Ultra 2 OneTouch UltraEasy OneTouch UltraLink OneTouch UltraMini OneTouch UltraSmart OneTouch UltraVue OneTouch Verio OneTouch VerioIQ OneTouch VerioPro OneTouch VerioPro+ OneTouch VerioSync OneTouch VerioVue OneTouch Vita SureStep Flexx	Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes Yes	GO GO GO GO GO GO GO GO GO GO GO GO GO GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GDH-FAD GO GO	Lifescan, Inc. www.lifescan.com Phone: 800-227-8862
Accu-Chek Active Accu-Chek Aviva Combo Accu-Chek Aviva Connect Accu-Chek Aviva Expert	Yes Yes Yes Yes	Mut Q-GDH Mut Q-GDH Mut Q-GDH Mut Q-GDH	Roche Diagnostics www.accu-chek.com Phone: 800-428-5076

Please see Indication and Important Risk Information for EXTRANEAL (icodextrin) PD Solution, including BOXED WARNING on pages 5-6. Please see the full [Prescribing Information](#) and [Medication Guide](#).

Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer
Accu-Chek Aviva Insight Accu-Chek Aviva Nano Accu-Chek Aviva Plus⁵ Accu-Chek Compact Plus Accu-Chek Inform II Accu-Chek Nano⁵ Accu-Chek Nano SmartView⁵ Accu-Chek Mobile Accu-Chek Performa Accu-Chek Performa Combo Accu-Chek Performa Connect Accu-Chek Performa Insight Accu-Chek Performa Nano	Yes Yes Yes⁵ Yes Yes Yes⁵ Yes⁵ Yes Yes Yes Yes Yes Yes	Mut Q-GDH Mut Q-GDH Mut-Q-GDH⁵ Mut Q-GDH Mut Q-GDH Mut Q-GDH⁵ Mut Q-GDH⁵ Mut Q-GDH Mut Q-GDH Mut Q-GDH Mut Q-GDH Mut Q-GDH Mut Q-GDH	
Accu-Chek Aviva⁴ Accu-Chek Aviva⁴	Yes⁴ No⁴	Mut-Q-GDH⁴ GDH-PQQ⁴	
Accu-Chek Advantage^A Accu-Chek Comfort Accu-Chek Compact Accu-Chek Complete System Accu-Chek Go/Go S System Accu-Chek GTS/GTS Plus Accu-Chek Inform System Accu-Chek Inform Accu-Chek Integra System Accu-Chek Plus Accu-Chek Sensor Accu-Chek Voicemate/Voice Mate Plus System	No No No No No No No No No No No No	GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ GDH-PQQ	
Nova Max Plus Nova Max Link StatStrip Hospital Glucose Meter StatStrip Hospital Glucose and Ketone Monitoring System StatStrip Xpress Glucose Meter StatStrip Xpress Glucose and Ketone Monitoring System Nova Pro Glucose/Ketone Meter	Yes Yes Yes Yes Yes Yes Yes	GO GO GO GO GO GO GDH-FAD	NovaBiomedical www.novabiomedical.com 781-894-0800
Jazz Presto iBGStar	Yes Yes Yes	GO GO GO	AgaMatrix, Inc. www.agamatrix.com 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. Consult manufacturer for additional information.

³ 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.

Please see Indication and Important Risk Information for EXTRANEAL (icodextrin) PD Solution, including BOXED WARNING on pages 5-6. Please see the full [Prescribing Information](#) and [Medication Guide](#).

⁵The ACCU-CHEK Nano (not Aviva or Performa) 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. Consult manufacturer for additional information.

⁶This/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

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

Extraneal Peritoneal Dialysis Solution Indication and Important Risk Information Indication:

EXTRANEAL (icodextrin) is indicated for a single daily exchange for the long (8- to 16- hour) 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:

WARNING: UNRECOGNIZED HYPOGLYCEMIA RESULTING FROM 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-FADbased glucose monitors and test strips has resulted in falsely elevated glucose readings (due to the presence of maltose). 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-FADbased blood glucose monitors and test strips are used.
- To avoid improper insulin administration, educate all patients to alert health care providers of this interaction particularly in hospital settings.
- 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.
- Because of the risk of unrecognized hypoglycemia that could result from a drug-device interaction, EXTRANEAL is available only through a restricted program.

- 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 is intended for intraperitoneal administration only. Not for intravenous injection. Aseptic technique should be used throughout the peritoneal dialysis procedure.
- Encapsulating peritoneal sclerosis (EPS), sometimes fatal, is a complication of peritoneal dialysis therapy and has been reported in patients using EXTRANEAL.

Please see Indication and Important Risk Information for EXTRANEAL (icodextrin) PD Solution, including BOXED WARNING on pages 5-6. Please see the full [Prescribing Information](#) and [Medication Guide](#).

- Serious hypersensitivity reactions to EXTRANEAL have been reported such as toxic epidermal necrolysis, angioedema, serum sickness, erythema multiforme and vasculitis. Anaphylactic or anaphylactoid reactions may occur. If a serious reaction is suspected, discontinue EXTRANEAL immediately and institute appropriate therapeutic countermeasures.
- Effective use of EXTRANEAL may be compromised in patients with abdominal conditions predisposing them to complications of peritoneal dialysis, including infection.
- Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be characterized by abdominal distention, feeling of fullness and/or shortness of breath. Drain the peritoneal dialysis solution from the peritoneal cavity to treat overinfusion.
- Patients with insulin-dependent diabetes may require modification of insulin dosage following initiation of treatment with EXTRANEAL. Monitor blood glucose and adjust insulin, if needed.
- Peritoneal dialysis may affect a patient's protein, water-soluble vitamin, potassium, sodium, chloride, bicarbonate, and magnesium levels and volume status. Monitor electrolytes and blood chemistry periodically. Monitor fluid status to avoid hyper- or hypovolemia and potentially severe consequences including congestive heart failure, volume depletion, and hypovolemic shock. Abnormalities in any of these parameters should be treated promptly under the care of a physician.
- In clinical trials, the most frequently reported adverse events occurring in $\geq 10\%$ of patients and more common in EXTRANEAL 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.

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 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.

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