Country-Specific Glucose Monitor List

Country Name: *United States*

Important Information

This is a non-comprehensive list, current as of *December 2017*. Absence of a specific glucose monitor or test strips from this list does NOT imply compatibility or incompatibility with EXTRANEAL (icodextrin) Peritoneal Dialysis 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 (icodextrin) Solution. **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 (icodextrin) Solution 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 monitor manufacturers listed have certified to Baxter that they have tested (as per 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 [4] for which certification of testing to Baxter's recommended limits has not yet been received. Please note that the compatibility list below is only for brand-name monitors used with the corresponding brand-name test strip. If a brand-name monitor is used with another manufacture's test strip, **always contact the test strip manufacturer for current 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) PD Solution.

1. EXTRANEAL (icodextrin) 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) solution, using these monitors or test strips, may mask true low blood sugar. This may cause a patient or health care professional to not take the appropriate steps to bring the blood sugar into a normal range. Alternatively, 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) 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 December 2017

Glucose Monitor Brand	Compatible with EXTRANEAL (icodextrin) PD Solution (Glucose-specific)	Test Type*	Manufacturer
FreeStyle Freedom	Yes	GDH-FAD	Abbott Diabetes Care www.abbottdiabetescare.com Phone: 888-522-5226
FreeStyle Freedom Lite	Yes	GDH-FAD	
FreeStyle InsuLinx	Yes	GDH-FAD	
FreeStyle Lite	Yes	GDH-FAD	
FreeStyle Optium[5]	Yes[5]	GDH-NAD[5]	
FreeStyle Optium H[5]	Yes[5]	GDH-NAD[5]	
FreeStyle Optium Neo[5]	Yes[5]	GDH-NAD[5]	
FreeStyle Optium Neo H[5]	Yes[5]	GDH-NAD[5]	
FreeStyle Papillon InsuLinx[5]	Yes[5]	GDH-FAD[5]	
FreeStyle Papillon Vision[5]	Yes[5]	GDH-FAD[5]	
FreeStyle Precision[5]	Yes[5]	GDH-NAD[5]	
FreeStyle Precision H	Yes	GDH-NAD	
FreeStyle Precision Neo	Yes	GDH-NAD	
FreeStyle Precision Neo H	Yes	GDH-NAD	
FreeStyle Precision Pro	Yes[5]	GDH-NAD[5]	
Optium[5]	Yes	GDH-NAD	
OptiumEZ	Yes[5]	GDH-NAD[5]	
Optium Xido[5]	Yes[5]	GDH-NAD[5]	
Optium Xido Neo[5]	Yes[5]	GDH-NAD[5]	
Precision Xceed Pro[5]	Yes	GDH-NAD	
Precision Xtra	Yes	GDH-NAD	
ReliOn Ultima			
Assure Platinum	Yes	GO	Arkray, Inc. www.arkrayusa.com Phone: 800-818-8877
Assure Prism[4]	Yes[4]	GO[4]	
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 MX	Yes	GDH-FAD	
GLUCOCARD MyDIA	Yes	GO	
GLUCOCARD Shine[4]	Yes[4]	GO[4]	
GLUCOCARD S	Yes	GDH-FAD	
GLUCOCARD SM	Yes	GDH-FAD	
GLUCOCARD Vital	Yes	GO	
GLUCOCARD X-meter[2]	Yes[2]	GDH-FAD[2]	
GLUCOCARD X-mini[2]	Yes[2]	GDH-FAD[2]	
GLUCOCARD X-mini plus[2]	Yes[2]	GDH-FAD[2]	
GLUCOCARD Σ	Yes	GO	
GLUCOCARD Σ-mini	Yes	GO	
ReliOn Confirm	Yes	GO	
ReliOn micro	Yes	GO	
ReliOn Prime	Yes	GO	

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

Glucose Monitor Brand	Compatible with EXTRANEAL (icodextrin) PD Solution (Glucose-specific)	Test Type*	Manufacturer
Breeze 2	Yes	GO	Ascensia Diabetes Care (formerly Bayer Healthcare) www.ascensia.com Phone: 800-348-8100
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	
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	
Contour Next One Blood	Yes	GDH-FAD	
Contour Plus One Blood	Yes	GDH-FAD	
OneTouch InDuo	Yes	GO	Lifescan, Inc. www.lifescan.com Phone: 800-227-8862
OneTouch Select	Yes	GO	
OneTouch Select Mini	Yes	GO	
OneTouch Select Simple	Yes	GO	
OneTouch Ultra[A]	Yes	GO	
OneTouch Ultra 2	Yes	GO	
OneTouch UltraEasy	Yes	GO	
OneTouch UltraLink	Yes	GO	
OneTouch UltraMini	Yes	GO	
OneTouch SelectPlus	Yes	GO	
OneTouch SelectPlus Flex	Yes	GO	
OneTouch UltraSmart	Yes	GO	
OneTouch UltraVue	Yes	GO	
OneTouch Verio	Yes	GDH-FAD	
OneTouch VerioFlex	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	
Nova Max Plus	Yes	GO	Nova Biomedical www.novabiomedical.com Phone: (781) 894-0800
Nova Max Link	Yes	GO	
StatStrip Hospital Glucose Meter	Yes	GO	
StatStrip Hospital Glucose and Ketone Monitoring System[5]	Yes[5]	GO[5]	
StatStrip Xpress Glucose Meter	Yes	GO	

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

Glucose Monitor Brand	Compatible with EXTRANEAL (icodextrin) PD Solution (Glucose-specific)	Test Type*	Manufacturer
StatStrip Xpress Glucose and Ketone Monitoring System[5]	Yes[5]	GO[5]	
StatStrip Xpress2 Glucose and Ketone Monitoring Meter	Yes	GO	
Nova Pro Glucose/Ketone Meter[5]	Yes[5]	GDH-FAD[5]	
Accu-Chek Active	Yes	Mut Q-GDH	Roche Diagnostics www.accu-chek.com Phone: 800-858-8072
Accu-Chek Aviva	Yes	Mut Q-GDH	
Accu-Chek Aviva Combo	Yes	Mut Q-GDH	
Accu-Chek Aviva Connect	Yes	Mut Q-GDH	
Accu-Chek Aviva Expert	Yes	Mut Q-GDH	
Accu-Chek Aviva Insight	Yes	Mut Q-GDH	
Accu-Chek Aviva Nano	Yes	Mut Q-GDH	
Accu-Chek Aviva Plus[3]	Yes[3]	Mut-Q-GDH[3]	
Accu-Chek Compact Plus	Yes	Mut Q-GDH	
Accu-Chek Guide	Yes	GDH-FAD	
Accu-Chek Inform II	Yes	Mut Q-GDH	
Accu-Chek Instant	Yes	GDH-FAD	
Accu-Chek Instant S	Yes	GDH-FAD	
Accu-Chek Nano[3]	Yes[3]	Mut Q-GDH[3]	
Accu-Chek Nano SmartView[3]	Yes[3]	Mut Q-GDH[3]	
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	
Accu-Chek Voicemate Plus System	Yes	Mut Q-GDH	
Jazz	Yes	GO	AgaMatrix, Inc. www.agamatrix.com Phone : 866-906-4197
Jazz Wireless 2	Yes	GO	
Presto	Yes	GO	
iBGStar	Yes	GO	
One Drop	Yes	GO	
TRUE Metrix[4]	Yes [4]	GDH-FAD[4]	Trividia Health (formerly Nipro Diagnostics) www.trividiahealth.com Phone: 800-803-6025
TRUE Metrix Air[4]	Yes [4]	GDH-FAD[4]	
TRUE Track[4]	Yes [4]	GDH-FAD[4]	
TRUE Balance[4]	Yes [4]	GDH-FAD[4]	
Prodigy AutoCode[4]	Yes[4]	GO[4]	Prodigy Diabetes Care www.prodigymeter.com Phone: 800-243-2636
Prodigy Voice[4]	Yes[4]	GO[4]	
Prodigy Pocket[4]	Yes[4]	GO[4]	
Prodigy No Coding Test Strips[4]	Yes[4]	GO[4]	
Embrace Pro[4]	Yes[4]	GDH-FAD[4]	Omnis Health www.omnishealth.com Phone: 877-979-5454

[1] Two types of compatible test strips for Precision Xtra OK.

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

[2] These Arkray monitors/test strips have switched from an **incompatible** GDH-FAD based chemistry to a **compatible** GDH-FAD based chemistry. Consult manufacturer for additional information.
[3] The 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.
[4] 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
[5] These brand name monitors are not available within United States.

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:
[A] Baxter report Interim 1, 33541 Determination of potential interference of icodextrin and its metabolites on human blood glucose measurement using chosen glucometers.

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

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

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 (icodextrin) 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-FAD-based 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-FAD-based 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 (icodextrin) 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 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.
- 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.
- 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 ≥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 reaction for EXTRANEAL PD Solution patients was skin rash.

Please see full Prescribing Information at www.baxter.com.

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