

## Country Specific Glucose Monitor List

**Country Name:** USA

### **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 monitor or test strips and 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(s) 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, or if they measure only glucose. Also, consult the product information included with the glucose monitor and test strips.
  - 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. **ONLY glucose-specific monitors and test strips should be used with patients on EXTRANEAL (icodextrin) PD solution.** Test strips are listed with their companion monitor - if you use other strips, contact the manufacturer to verify that they are glucose-specific. The list provides the contact information of the more common, major brands of monitors/test strip manufacturers.
  - This is a non-comprehensive list, current as of February, 2013. Absence of your specific glucose monitor or test strips from this list does **NOT** 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 February 2013

| Glucose Monitor Brand | Compatible with Extraneal<br>(icodextrin) PD solution<br>(Glucose-specific) | Test Type* | Manufacturer   |
|-----------------------|---|------------|--|
| Boots                 | Yes   | GDH-NAD    | Abbott Diabetes Care<br><a href="http://www.abbottdiabetescare.com">www.abbottdiabetescare.com</a><br>888-522-5226 |
| Freestyle Navigator   | Yes   | GDH-FAD    |  |
| Freestyle Optium      | Yes   | GDH-NAD    |  |
| Freestyle Optium H    | Yes   | GDH-NAD    |  |
| Freestyle Precision   | Yes   | GDH-NAD    |  |
| Freestyle Precision H | Yes   | GDH-NAD    |  |
| Omron HEA-214         | Yes   | GDH-NAD    |  |
| Optium                | Yes   | GDH-NAD    |  |
| Optium Easy           | Yes   | GDH-NAD    |  |
| OptiumEZ              | Yes   | GDH-NAD    |  |

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|  |                  |                          |   |
|--|------------------|--------------------------|---|
| Optium Xceed                           | Yes              | GDH-NAD                  |   |
| Optium Xido                            | Yes              | GDH-NAD                  |   |
| Precision PCx                          | Yes <sup>1</sup> | GDH-NAD, GO <sup>1</sup> |   |
| Precision QID <sup>B</sup>             | Yes              | GO                       |   |
| Precision Xceed                        | Yes              | GDH-NAD                  |   |
| Precision Xceed Pro                    | Yes              | GDH-NAD                  |   |
| Precision Xtra                         | Yes              | GDH-NAD                  |   |
| Precision Xtra OK                      | Yes <sup>1</sup> | GDH-NAD, GO <sup>1</sup> |   |
| ReliOn Ultima                          | Yes              | GDH-NAD                  |   |
| Sof-Sense                              | Yes              | GDH-NAD                  |   |
| Sof-Tact <sup>C</sup>                  | Yes              | GDH-NAD                  |   |
| TrueSense                              | Yes              | GDH-NAD                  |   |
| FreeStyle <sup>2</sup>                 | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle <sup>2</sup>                 | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Flash <sup>2</sup>           | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Flash <sup>2</sup>           | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Freedom <sup>2</sup>         | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Freedom <sup>2</sup>         | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Freedom Lite <sup>2</sup>    | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Freedom Lite <sup>2</sup>    | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Lite <sup>2</sup>            | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Lite <sup>2</sup>            | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Mini <sup>2</sup>            | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Mini <sup>2</sup>            | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Papillon <sup>2</sup>        | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Papillon <sup>2</sup>        | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Papillon Lite <sup>2</sup>   | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Papillon Lite <sup>2</sup>   | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Papillon Mini <sup>2</sup>   | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Papillon Mini <sup>2</sup>   | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| FreeStyle Papillon Vision <sup>2</sup> | Yes <sup>2</sup> | GDH-FAD <sup>2</sup>     |   |
| FreeStyle Papillon Vision <sup>2</sup> | No <sup>2</sup>  | GDH-PQQ <sup>2</sup>     |   |
| CoZmonitor                             | No               | GDH-PQQ                  |   |
| FreeStyle Tracker                      | No               | GDH-PQQ                  |   |
| Optium Mini                            | No               | GDH-PQQ                  |   |
| Optium Omega                           | No               | GDH-PQQ                  |   |
| Advance Intuition                      | Yes              | GO                       |   |
| Assure Platinum                        | Yes              | GO                       |   |
| Assure Pro                             | Yes              | GO                       |   |
| Assure 4                               | Yes              | GO                       |   |
| GLUCOCARD 01                           | Yes              | GO                       |   |
| GLUCOCARD 01-mini                      | Yes              | GO                       |   |
| GLUCOCARD Expression                   | Yes              | GO                       |   |
| GLUCOCARD Vital                        | Yes              | GO                       |   |
| PocketChem EZ                          | Yes              | GO                       |   |
| GLUCOCARD X-meter <sup>D</sup>         | No <sup>3</sup>  | GDH-FAD <sup>3</sup>     |   |
| Ascensia Breeze                        | Yes              | GO                       |   |
| Ascensia Brio                          | Yes              | GO                       | Arkray, Inc.<br><a href="http://www.arkrayusa.com">www.arkrayusa.com</a><br>800-818-8877, Option #5 |
|  |                  |                          | Bayer Healthcare  |

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|                                       |                  |                        |   |
|---------------------------------------|------------------|------------------------|---|
| Ascensia Confirm                      | Yes              | GO                     | <a href="http://www.bayerdiabetes.com">www.bayerdiabetes.com</a><br>800-348-8100  |
| Ascensia Dex                          | Yes              | GO                     |   |
| Ascensia Entrust                      | Yes              | GO                     |   |
| Ascensia Esprit                       | Yes              | GO                     |   |
| Breeze 2                              | Yes              | GO                     |   |
| Contour                               | Yes              | GDH-FAD                |   |
| Contour Link                          | Yes              | GDH-FAD                |   |
| Contour Next EZ                       | Yes              | GDH-FAD                |   |
| Contour TS                            | Yes              | GDH-FAD                |   |
| Contour USB                           | Yes              | GDH-FAD                |   |
| Contour XT                            | Yes              | GDH-FAD                |   |
| Didget                                | Yes              | GDH-FAD                |   |
| Elite                                 | Yes              | GO                     |   |
| OneTouch InDuo                        | Yes              | GO                     | Lifescan, Inc.<br><a href="http://www.lifescan.com">www.lifescan.com</a><br>800-524-SCAN<br>800-227-8862  |
| One Touch Ping                        | Yes              | GO                     |   |
| OneTouch Select                       | Yes              | GO                     |   |
| OneTouch Select Mini                  | Yes              | GO                     |   |
| OneTouch Select Simple                | Yes              | GO                     |   |
| OneTouch SureStep                     | Yes              | GO                     |   |
| OneTouch Ultra <sup>E</sup>           | Yes              | GO                     |   |
| OneTouch Ultra Easy                   | Yes              | GO                     |   |
| OneTouch Ultra 2                      | Yes              | GO                     |   |
| One TouchUltraLink                    | Yes              | GO                     |   |
| OneTouch UltraMini                    | Yes              | GO                     |   |
| OneTouch UltraSmart                   | Yes              | GO                     |   |
| One Touch UltraVue                    | Yes              | GO                     |   |
| OneTouch Verio                        | Yes              | GDH-FAD                |   |
| OneTouch Verio IQ                     | Yes              | GDH-FAD                |   |
| One Touch VerioPro                    | Yes              | GDH-FAD                |   |
| One Touch Vita                        | Yes              | GO                     |   |
| SureStep Flexx                        | Yes              | GO                     |   |
| Accu-Chek Nano <sup>5</sup>           | Yes <sup>5</sup> | Mut Q-GDH <sup>5</sup> | Roche Diagnostics<br><a href="http://www.roche-diagnostics.com">www.roche-diagnostics.com</a><br><a href="http://www.accu-chek.com">www.accu-chek.com</a><br>800-858-8072 |
| Accu-Chek Aviva <sup>4</sup>          | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Aviva <sup>4</sup>          | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Aviva Combo <sup>4</sup>    | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Aviva Combo <sup>4</sup>    | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Aviva Expert <sup>4</sup>   | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Aviva Expert <sup>4</sup>   | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Aviva Nano <sup>4</sup>     | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Aviva Nano <sup>4</sup>     | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Compact Plus <sup>A,4</sup> | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Compact Plus <sup>A,4</sup> | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Inform II <sup>4</sup>      | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Inform II <sup>4</sup>      | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Mobile <sup>4</sup>         | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Mobile <sup>4</sup>         | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Performa <sup>4</sup>       | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Performa <sup>4</sup>       | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Performa Nano <sup>4</sup>  | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Performa Nano <sup>4</sup>  | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |
| Accu-Chek Performa Combo <sup>4</sup> | Yes <sup>4</sup> | Mut Q-GDH <sup>4</sup> |   |
| Accu-Chek Performa Combo <sup>4</sup> | No <sup>4</sup>  | GDH-PQQ <sup>4</sup>   |   |

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|   |            |                |  |
|---|------------|----------------|--|
| <b>Accu-Chek Active/S System</b>                  | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Advantage <sup>A</sup></b>           | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Comfort</b>                          | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Compact</b>                          | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Complete System</b>                  | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Go/Go S System</b>                   | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek GTS/GTS Plus</b>                     | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Inform System</b>                    | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Inform</b>                           | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Integra System</b>                   | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Plus</b>                             | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Sensor</b>                           | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Accu-Chek Voicemate/Voice Mate Plus System</b> | <b>No</b>  | <b>GDH-PQQ</b> |  |
| <b>Nova Max Plus</b>                              | <b>Yes</b> | <b>GO</b>      | <b>NovaBiomedical</b>  |
| <b>Nova Max Link</b>                              | <b>Yes</b> | <b>GO</b>      | <a href="http://www.novabiomedical.com">www.novabiomedical.com</a> |
| <b>StatStrip Hospital</b>                         | <b>Yes</b> | <b>GO</b>      | 800-458-5813   |
| <b>StatStrip Xpress</b>                           | <b>Yes</b> | <b>GO</b>      | 781-894-0800   |
| <b>iBGStar</b>                                    | <b>Yes</b> | <b>GO</b>      | <b>AgaMatrix, Inc.</b>   |
| <b>Liberty</b>                                    | <b>Yes</b> | <b>GO</b>      | <a href="http://www.agamatrix.com">www.agamatrix.com</a>           |
| <b>Liberty II</b>                                 | <b>No</b>  | <b>GDH-PQQ</b> | 866-906-4197   |

<sup>1</sup> Two types of **compatible** test strips for Precision PCx and Precision Xtra OK.

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

<sup>3</sup> This Arkray GDH-FAD monitor/test strip is **incompatible**. Consult manufacturer for additional information.

<sup>4</sup> These brand name monitors can utilize either GDH-PQQ (**incompatible**) or **Mut Q-GDH (compatible)** strips. Consult manufacturer for additional information.

<sup>5</sup> The Accu-Chek Nano meter (but not Accu-Chek Aviva or Accu-Chek Performa) is available ONLY in the United States and uses strips branded as **Accu-Chek Smartview**. Accu-Chek Smartview strips use the **MUT Q-GDH (compatible)** chemistry.

#### 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:

<sup>A</sup> Baxter study 32386 Determination of potential interference of icodextrin and its metabolites on human blood glucose measurement using Accu-Chek compact and Advantage systems.

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

<sup>C</sup> Baxter report RD-01-RE-233 Evaluation of potential interference in the blood glucose test kit MediSense Sof-Tact with icodextrin and its metabolites.

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<sup>D</sup> 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).

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

### **Important Risk Information for Extraneal (icodextrin) Peritoneal Dialysis Solution**

#### **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.glucosafety.com](http://www.glucosafety.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** 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.

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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

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AL13039 02/2013

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