

## **Country-Specific Glucose Monitor List**

**Country Name:** Malta

### **Important Information**

This is a non-comprehensive list, current as of **November 2021**. 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 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 mentioned below showed no interference of blood glucose readings. 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) 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 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) 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.

### **Reporting of suspected adverse reactions to the Malta Medicines Authority**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

Alternatively, any suspected adverse reactions can also be reported to Malta Medicines Authority Post-Licensing Directorate, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta

### **Reporting of suspected adverse reactions to the Marketing Authorisation Holder**

Suspected adverse reactions to Baxter products can also be reported direct to Baxter Pharmacovigilance on +44 (0)1635 206360, or by email to [vigilanceuk@baxter.com](mailto:vigilanceuk@baxter.com)

## GLUCOSE MONITORS

Updated November 2021

Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer
FreeStyle Freedom	Yes	GDH-FAD	Abbott Diabetes Care <a href="http://www.abbottdiabetescare.com">www.abbottdiabetescare.com</a> Phone: +356 2145 4166
FreeStyle Freedom Lite	Yes	GDH-FAD	
FreeStyle Lite	Yes	GDH-FAD	
FreeStyle Libre <sup>1</sup>	Not Recommended	GO	
FreeStyle Libre Pro <sup>1</sup>	Not Recommended	GO	
FreeStyle Libre 2 <sup>1</sup>	Not Recommended	GO	
FreeStyle Libre 3 <sup>1</sup>	Not Recommended	GO	
FreeStyle Optium Neo	Yes	GDH-NAD	
FreeStyle Optium Neo H	Yes	GDH-NAD	
FreeStyle Papillon Vision	Yes	GDH-FAD	
FreeStyle Precision Neo	Yes	GDH-NAD	
FreeStyle Precision Pro	Yes	GDH-NAD	
Optium Xido Neo	Yes	GDH-NAD	
Precision Xceed Pro	Yes	GDH-NAD	
Assure Platinum	Yes	GO	Arkray, Inc. <a href="http://www.arkray.co.jp">www.arkray.co.jp</a> Phone: N/A
GLUCOCARD 01	Yes	GO	
GLUCOCARD 01-mini	Yes	GO	
GLUCOCARD 01-mini plus	Yes	GO	
GLUCOCARD MX	Yes	GDH-FAD	
GLUCOCARD S	Yes	GDH-FAD	
GLUCOCARD SM	Yes	GDH-FAD	
GLUCOCARD Vital	Yes	GO	
GLUCOCARD X-meter <sup>2</sup>	Yes	GDH-FAD	
GLUCOCARD X-mini <sup>2</sup>	Yes	GDH-FAD	
GLUCOCARD X-mini plus <sup>2</sup>	Yes	GDH-FAD	
GLUCOCARD Σ	Yes	GO	
GLUCOCARD Σ-mini	Yes	GO	
ReliOn Confirm	Yes	GO	
ReliOn micro	Yes	GO	
ReliOn Prime	Yes	GO	
GLUCOCARD S onyx	Yes	GDH-FAD	
PocketChem BG	Yes	GDH-FAD	
GLUCOCARD W	Yes	GO	
GLUCOCARD PlusCare	Yes	GDH-FAD	
GLUCOCARD Prime	Yes	GDH-FAD	
GLUCOCARD G+	Yes	GO	
GLUCOCARD G+ Link	Yes	GO	



Glucose Monitor Brand	Compatible with Extraneal (Icodextrin) PD solution (Glucose-specific)	Test Type*	Manufacturer	
Nova Max Plus	Yes	GO	Nova Biomedical <a href="http://www.novabiomedical.com">www.novabiomedical.com</a> Phone: N/A	
Nova Max Link	Yes	GO		
StatStrip Hospital Glucose Meter	Yes	GO		
StatStrip Hospital Glucose and Ketone Monitoring System	Yes	GO		
StatStrip Xpress Glucose Meter	Yes	GO		
StatStrip Xpress Glucose and Ketone Monitoring System	Yes	GO		
StatStrip Xpress2 Glucose and Ketone Monitoring System	Yes	GO		
Nova Pro Glucose/Ketone Meter	Yes	GDH-FAD		
Accu-Chek Active	Yes	Mut Q-GDH		Roche Diagnostics <a href="http://www.accu-chek.com">www.accu-chek.com</a> Phone: +356 2134 4610
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 Plus <sup>3</sup>	Yes	Mut Q-GDH		
Accu-Check Aviva Solo	Yes	Mut Q-GDH		
Accu-Chek Guide	Yes	GDH-FAD		
Accu-Chek Guide Me	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 <sup>3</sup>	Yes	Mut Q-GDH		
Accu-Chek Nano SmartView <sup>3</sup>	Yes	Mut Q-GDH		
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-Check Performa Solo	Yes	Mut Q-GDH		
Accu-Chek Guide Insight	Yes	GDH-FAD		
TRUE METRIX	Yes	GDH-FAD	Trividia Health <a href="http://www.trividiahealth.com">www.trividiahealth.com</a> Phone: N/A	
TRUE METRIX GO	Yes	GDH-FAD		
TRUE METRIX Air	Yes	GDH-FAD		
TRUEresult <sup>4</sup>	Not Recommended	GDH-FAD		
TRUEresult Twist 2 <sup>4</sup>	Not Recommended	GDH-FAD		
TRUEyou <sup>4</sup>	Not Recommended	GDH-FAD		
TRUEtrack <sup>4</sup>	Not Recommended	GO		
TRUEresult	No	GDH-PQQ		

<sup>1</sup> These Abbott monitors (together with the Dexcom G4 Platinum, G5 Mobile, G6 and the Medtronic iPro2) are the leading Continuous Glucose Monitor Systems (CGM) and are **not recommended** by their manufacturers for use into dialysis patients, and despite having a GO based chemistry currently there is not definitive scientific evidence for their Extraneal compatibility. Consult manufacturer for additional information.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> TRUEresult (GDH-FAD), TRUEresult Twist 2, TRUEyou, True track monitors were not tested with the Baxter recommended limits for Icodextrin and Maltose. So, these monitors were **not recommended** to use for dialysis patients.

#### **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 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.

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