FREESENS®

Accuracy Beyond Standards

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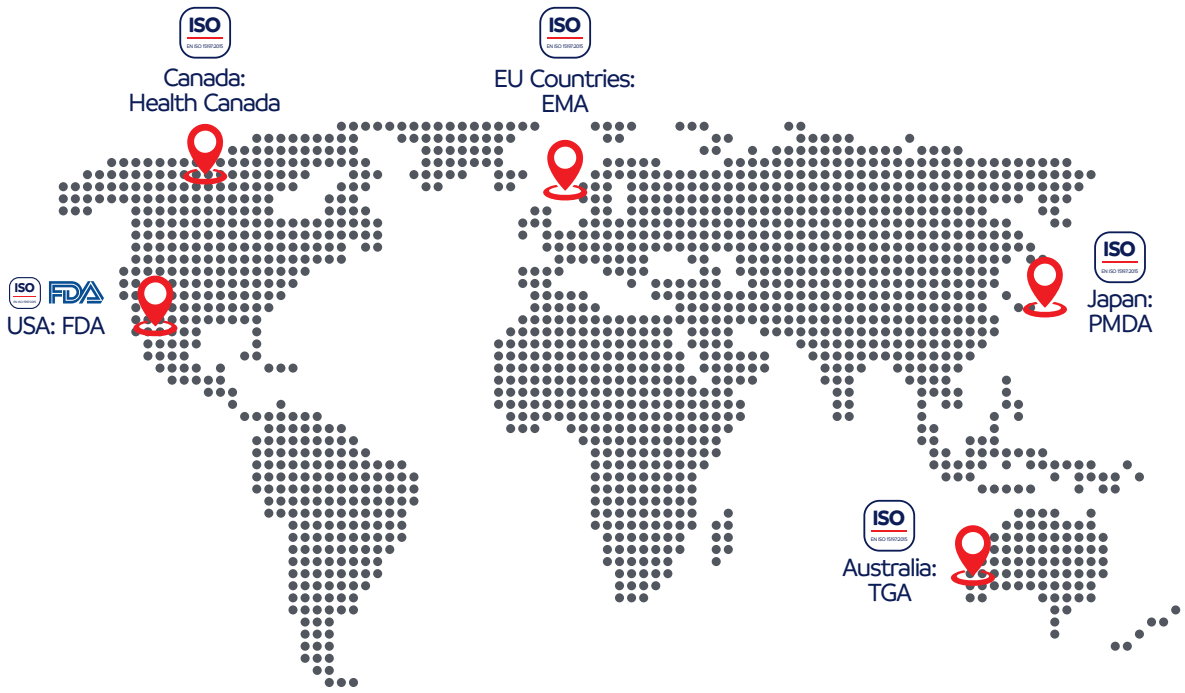
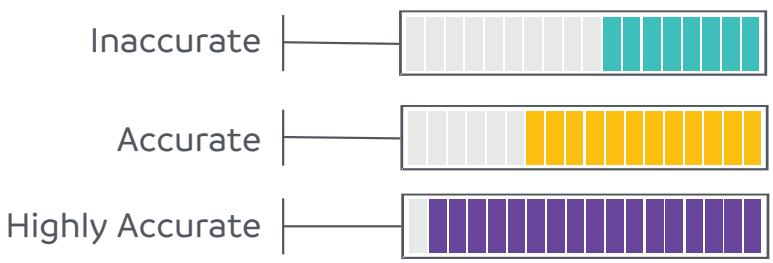
Guidelines for Approval of Glucose Monitoring Devices



FREESENS: Highly Accurate Results

	ISO 15197:2015			FDA OTC 2020	
BS Range	BS<100	BS ≥ 100	CEG	Entire range	
Bias	±15 mg/dL	±15%	Zone A+B	±15%	±20%
Minimum Accuracy	95%	95%	99%	95%	99%
FREESENS/Easymax	**100%**	**99.3%**	**100%**	**96.6%**	**99.6%**



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FREESENS: Cutting Edge BGM Technology

Hematocrit Correction:

Applying AC voltage to the blood sample and processing the electric response signal, the system can calculate HCT and compensate the inaccuracies related to HCT variation.

Clinical Implication:

-Wide hematocrit range coverage: 10-65%
-Accurate readings in specific populations including smokers, pregnant women and neonates.

No Coding Technology:

High Quality Enzyme Purification and Precise Enzyme Dispensing

Clinical Implication:

–Ease of use
–Improved accuracy due to reduction in Lot-to-lot variability
–Eliminating miscoding errors

Temperature Correction:

Using both built-in temperature sensor and multi sensor predictive algorithm to compensate for temperature variability.

Clinical Implication:

–Accurate readings when temperature changes within the working range
–Report error codes “Ht” or “Lt” when the ambient temperature is out of the working range.

Dual Under Filling Detection:

Using both the extra electrode and insufficient sample detection algorithm to ensure the elimination of all under filling related inaccuracies.

Clinical Implication:

– Accurate results in patients prone to insufficient blood sampling, such as uneducated patients, children and those with hand tremor
– Report error code “E-2” in case of insufficient blood sample volume.

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FREESENS: Advanced Strip Chemistry

Advanced Enzyme:

Higher accuracy by using GDH-FAD enzyme and an specific mediator

Clinical Implication :

- Accurate results in patients with respiratory diseases or under oxygen therapy.
- Accurate results with both venous and capillary whole blood samples.
- After opening, test strips can be used up to 6 months.
- 2-year shelf-life

Minimum Interference:

High substrate specificity with no interference from 61 substances

Clinical Implication:

- Covers majority of endogenic and exogenic substance including uric acid, acetaminophen, salicylates, ascorbic acid, maltose, galactose and commonly prescribed DM and HTN medications.
- Accurate readings in patients with kidney failure, heart failure, HTN and inherited metabolic disorders like galactosemia.

		FREESENS	Glucocard 01
Accuracy ISO 15197 : 2015	BS <100 Within ±15 mg/dl	100%	100%
	BS ⩾100 Within ±15%	99.3%	96.5%
Coding Technology		No Coding	Auto Coding
Test Time		5 Seconds	7 Seconds
Hematocrit Range		10 - 65 %	35 - 50 %
Enzyme		GDH - FAD	GOD
Memory Capacity		880	50
Color Indicator		+	-
Pre/Post Meal Indicator		+	+
Connectivity		+(NFC)	-
Sample Volume - (µL)		0.6	0.3

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