MetaDR[™] is FDA registered!

New Search	FDA U.S. FOOD & DRUG	Back To Search Results
Proprietary Name:	MetaDRTM Breath Ketone Sensor; MetaNoseTM Breath Acetone Sensor	
Classification Name:	NITROPRUSSIDE, KETONES (URINARY, NON-QUANT.)	
Product Code:	JIN	
Device Class:	1	
Regulation Number:	862.1435	
Medical Specialty:	Clinical Chemistry	
Registered Establishment Name:	FOCUS FULL LIMITED	
Owner/Operator:	Focus Full Limited	
Owner/Operator Number:	10085283	
Establishment Operations:	Manufacturer	

Diabetic ketoacidosis (DKA) is a serious problem that can happen in people with diabetes if their body starts to run out of insulin. DKA is the leading cause of mortality among children and young adults with type 1 diabetes, accounting for 50% of all deaths in this population. DKA is also increasingly found among type 2 diabetic patients, which poses a significant threat for 415 million population who suffer from diabetes worldwide. (CDC, USA)

DKA, If not treated, can lead to a diabetic coma and death within hours.

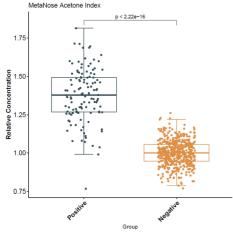


Figure 1: preliminary study of 120 ketosis subjects and 500 control subjects.

Highlights MetaDR[™]

- Proprietary IC design for state-ofthe-art MEMS Sensor
- Proprietary sensor data processing algorithm
- Consistent blood glucose level Management
- High accuracy of breath acetone for Diabetic Ketoacidosis (DKA) patients
- Research capability based on exclusive access to 50,000 human breath database
- Next generation of diabetic risk monitoring device

How MetaDR[™]works

Simply exhale into the device for 5 seconds. Results will be shown on the screen in real time.



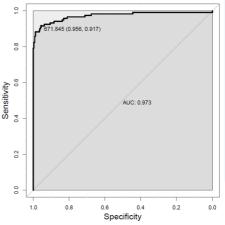


Figure 2: an optimal sensitivity of 91.7% and specificity of 95.6% has been achieved.

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