

SMBG/FGM/CGM

WHICH WILL HELP THE PATIENTS MOST?



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Past President RSSDI

Past President API (UP Chapter)

President Women in Endocrinology and Diabetes (WENDI)

Founder President South Asian Federation of Endocrine Societies

Past President Endocrine Society of India

MONITORING

Intensification

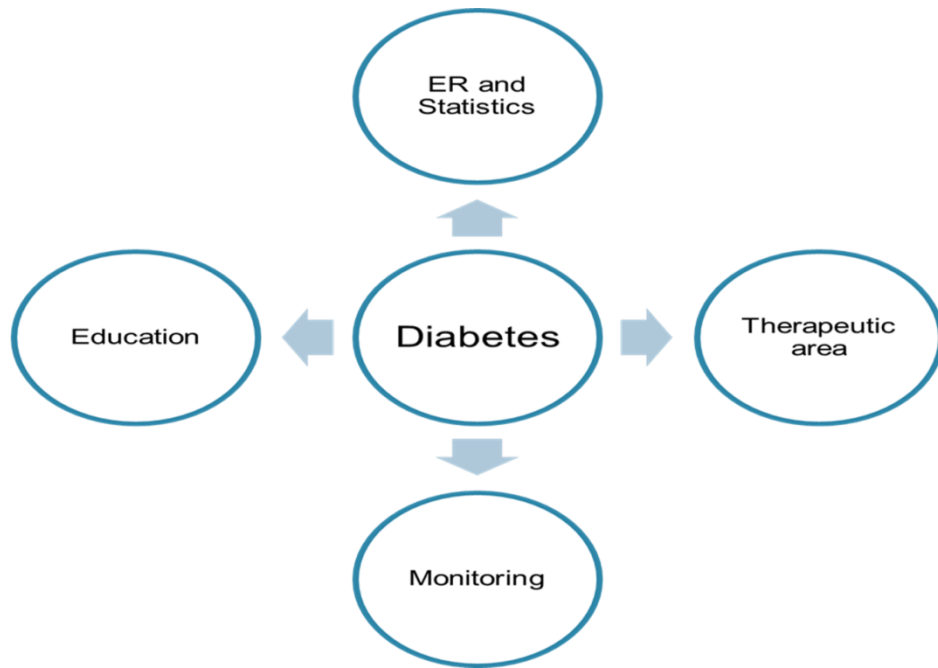
- Type 1
- Type 2
- GDM

- Aim to keep A1C < 7%
- ??? Achievable



Poor
control

HbA1c
< 7%



Diabetes  *Monitoring*

Improving Glycemic Control

TREAT TO TARGET

“Change the way you see your blood sugar”

Who should monitor glycemia?



**Patient
Self-monitoring
of blood glucose**

**Healthcare
professionals
Regular monitoring
of A1C**

Diabetes care team

**Combined synergistic efforts of
team are crucial to ensure effective
monitoring of blood glucose**

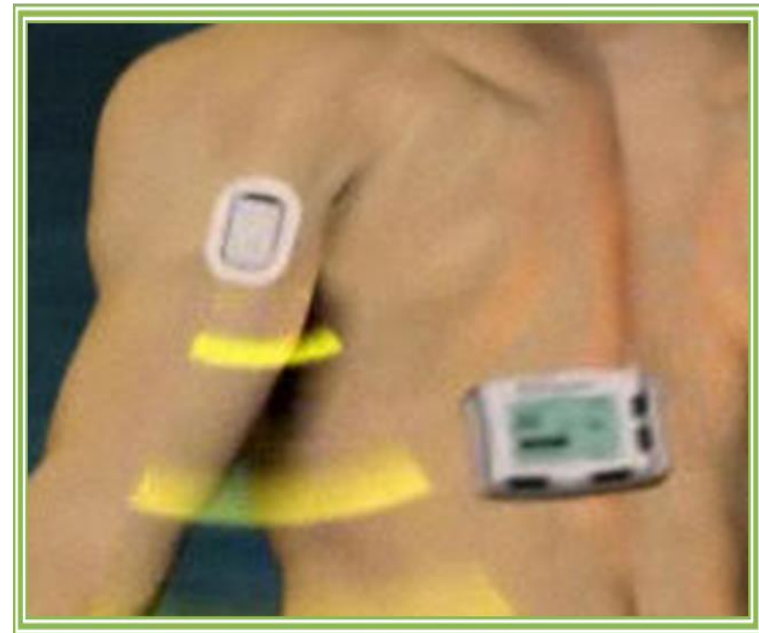


Glucose Monitoring

an **T**cient method



modern method



BG Test-strip Technology: Enzyme/mediator Systems

- **Glucose oxidase: specific for glucose but susceptible to pO₂ effect**
- **GDH-PQQ: eliminates oxygen effect but is less specific, but also detects maltose and galactose**
- **HK-G6PDH: eliminates oxygen effect but is more sensitive to heat and humidity**
- **Mediators ('electron transfer molecules') : Key Breakthrough Help to minimize interference especially when using low potential mediators, improved with a third electrodes**



Embrace Talking Blood Glucose Meter

Product ID: PMEOMH01AB0200
Manufacturer: OMNIS HEALTHCARE
Manufacturer Part Number: H01AB0200



Invacare® TrueTrack™ Smart System Blood Glucose Monitoring System

Product ID: INVISG172200
Manufacturer: Invacare® Supply Group
Manufacturer Part Number: ISG172200
Packaging: Each



Accu-Chek® Compact™ Blood Glucose Meter Kit

Product ID: INV BIO3149137
Manufacturer: Boehringer Mannheim
Manufacturer Part Number: BIO3149137



FreeStyle® Freedom Lite Blood Glucose Monitoring System

Product ID: INVTSI70914
Manufacturer: Abbott Diabetes Care
Manufacturer Part Number: TSI70914
Packaging: Each



ONE TOUCH® UltraSmart™ System Kit

Product ID: INV LFS020524
Manufacturer: LifeScan
Manufacturer Part Number: LFS020524
ONE TOUCH® UltraSmart™ System Kit
More...



Accu-Chek® Active Blood Glucose Monitor Kit

Product ID: INV BIO3184501
Manufacturer: Roche Diagnostics
Manufacturer Part Number: BIO3184501
Packaging: Each



ASCENSIA® BREEZE 2™ Blood Glucose Monitoring System

Product ID: INVAMS1440
Manufacturer: Bayer Diagnostic
Manufacturer Part Number: AMS1440
Packaging: Each



Ascensia® CONTOUR™ Blood Glucose Monitoring System

Product ID: INVAMS7151
Manufacturer: Bayer Diagnostic
Manufacturer Part Number: AMS7151
Packaging: Each



One TOUCH® Ultra Blood Glucose Monitoring System

Product ID: INV LFS020247
Manufacturer: LifeScan
Manufacturer Part Number: LFS020247
One TOUCH® Ultra Blood Glucose Monitoring System



OneTouch® Ultra2 Blood Glucose Meter

Product ID: INV LFS021098
Manufacturer: LifeScan
Manufacturer Part Number: LFS021098
Packaging: Each
OneTouch® Ultra2 Blood Glucose Meter. Kit.
..

How to select a glucose meter



Embrace Meter Kit with 3 Months of Supplies

Product ID: PMEEMBRACEMETERKIT
Manufacturer: OMNIS HEALTHCARE
Manufacturer Part Number: EMBRACEMETERKIT
Packaging: 1, 2, 3, 4 Times Daily



Embrace Talking Blood Glucose Meter

Product ID: PMEOMH01AB0200
Manufacturer: OMNIS HEALTHCARE
Manufacturer Part Number: H01AB0200
Packaging: Each



Fora V10 Meter Kit with 3 Months of Supplies

Product ID: PMEFORAV10METERKIT

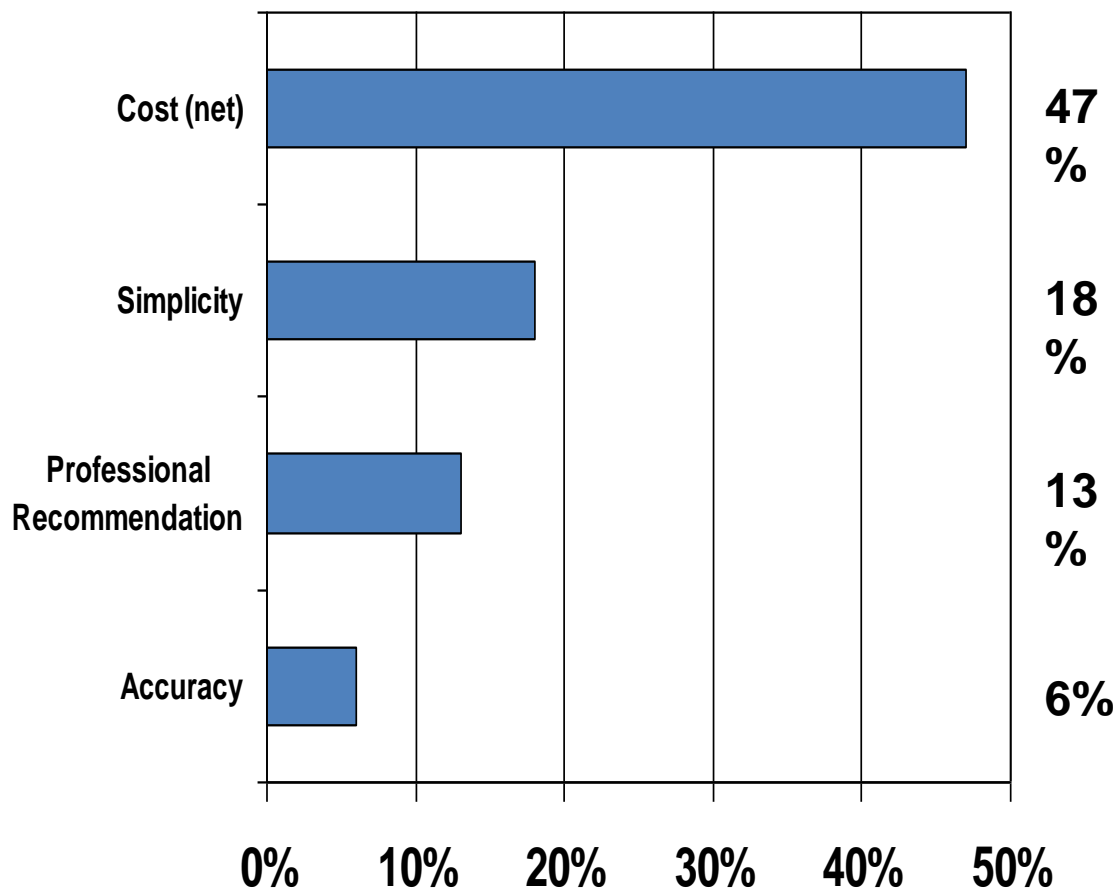


Infinity Meter Kit with 3 Months of Supplies

Product ID: PMEINFINITYMETERKIT



Patient's Reasons for Selecting a BG Meter



2006 Roper Global US Diabetes Program at GFK NOP World Health, August – September 2006

Specifications we look for

Size	No routine maintenance	Range from 20 to 600 mg/dl	Reading time less than 10 seconds	Electrochemical technology
blood sample less than 1.5µl	LCD display Auto power off	Unit in mg/dl.	Wide operating temperature Humidity	Memory
Life time replacement offer	Easy code entry /no code	Battery type & life	Facility to ensure accuracy.	Control solutions
		Certificate CE / FDA /ISO		

Why you should invest on a good BGM system

1

**Cost-effective :
Spend a little
Save in millions**

2

**Prevent chronic complications
(MI, stroke, amputations, eye disease, renal failure)**

3

**Prevent acute complications
hypos, DKA, HONK**

4

**Type 1
Type 2
Gestational diabetes**

Economics- SMBG at least 1/day could reduce financial risk to patients

Complication cost factor	Risk-adjusted cost for no SMBG cohort (INR)	Risk-adjusted cost for single SMBG per day cohort (INR)
Cost of complications		
Cardiovascular	127,997	115,172
Foot	461,635	311,466
Ocular	185,407	159,980
Renal	58,351	42,227
Hypoglycemia	5,123	5123
Cost of monitoring with SMBG		
Cost of 7 SMBG tests/week	0	82,832
Cost of SMBG meter	0	1540
Total costs over 10 years, discounted to present value	838,513	718,340

SMBG: Self-monitoring of blood glucose, INR: Indian rupee

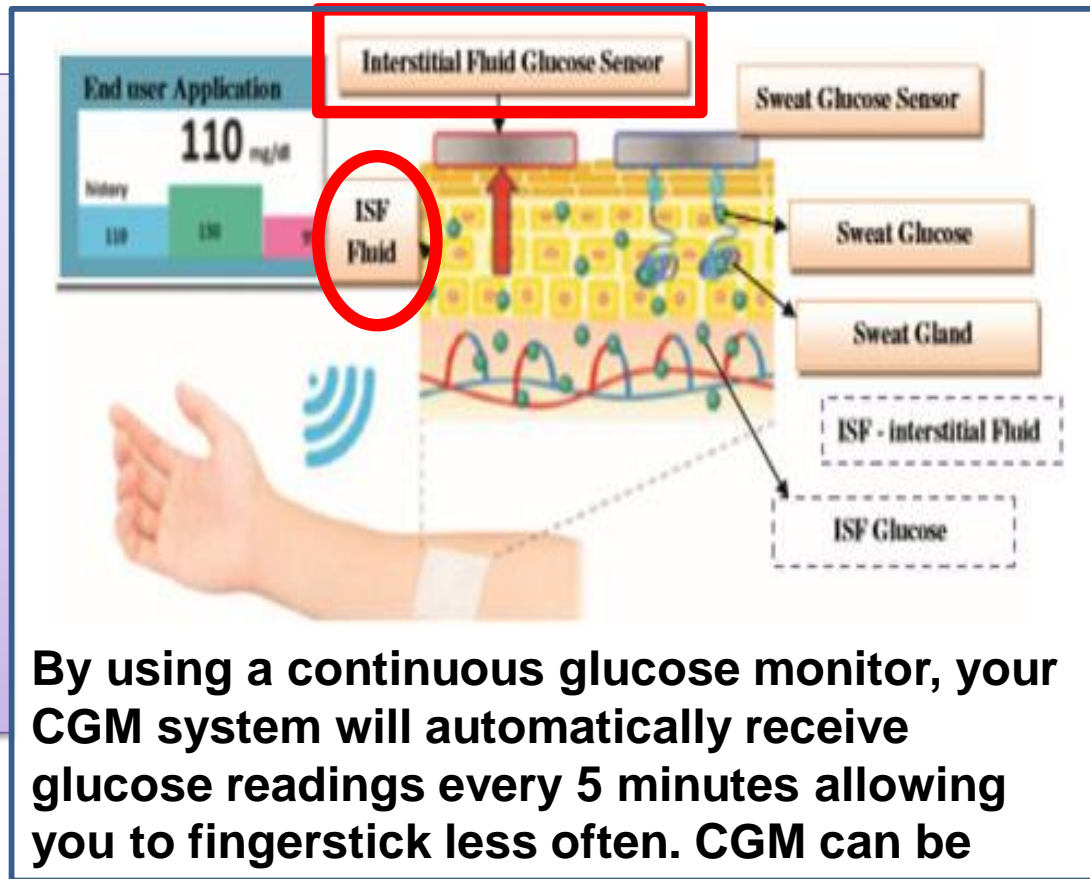
Component	Cost in INR	Source
Cost of monitoring with SMBG		
SMBG per test	26	JnJ India
SMBG (m)	1540	JnJ India
Cost of complications		
Severe hypoglycaemic event (event cost)	5070	Expert opinion (Indian physicians)
Cardiovascular complications (annual cost)	214,236	Kumpatla <i>et al.</i> 2013 ^[15]
Foot complications (annual cost)	160,677	Kumpatla <i>et al.</i> 2013 ^[15]
Eye complications (annual cost)	107,118	Kumpatla <i>et al.</i> 2013 ^[15]
Renal complications (annual cost)	107,118	Kumpatla <i>et al.</i> 2013 ^[15]

INR: Indian rupee, SMBG: Self-monitoring of blood glucose

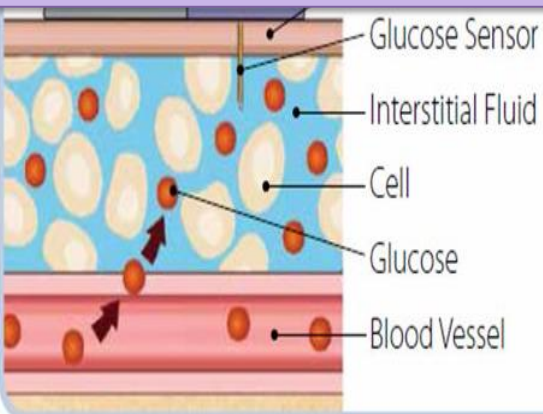
Mohan et al. Indian J Endocrinol Metab. 2018 Jul-Aug; 22(4): 461–465.

What is CGM ?

Continuous Glucose Monitoring (CGM) is a method to track glucose levels in interstitial fluid throughout the day and night. CGM systems take glucose measurements at regular intervals, 24 hours a day, and translate the readings into dynamic data, generating glucose direction and rate of change reports.



By using a continuous glucose monitor, your CGM system will automatically receive glucose readings every 5 minutes allowing you to fingerstick less often. CGM can be used with or without an insulin pump.¹¹

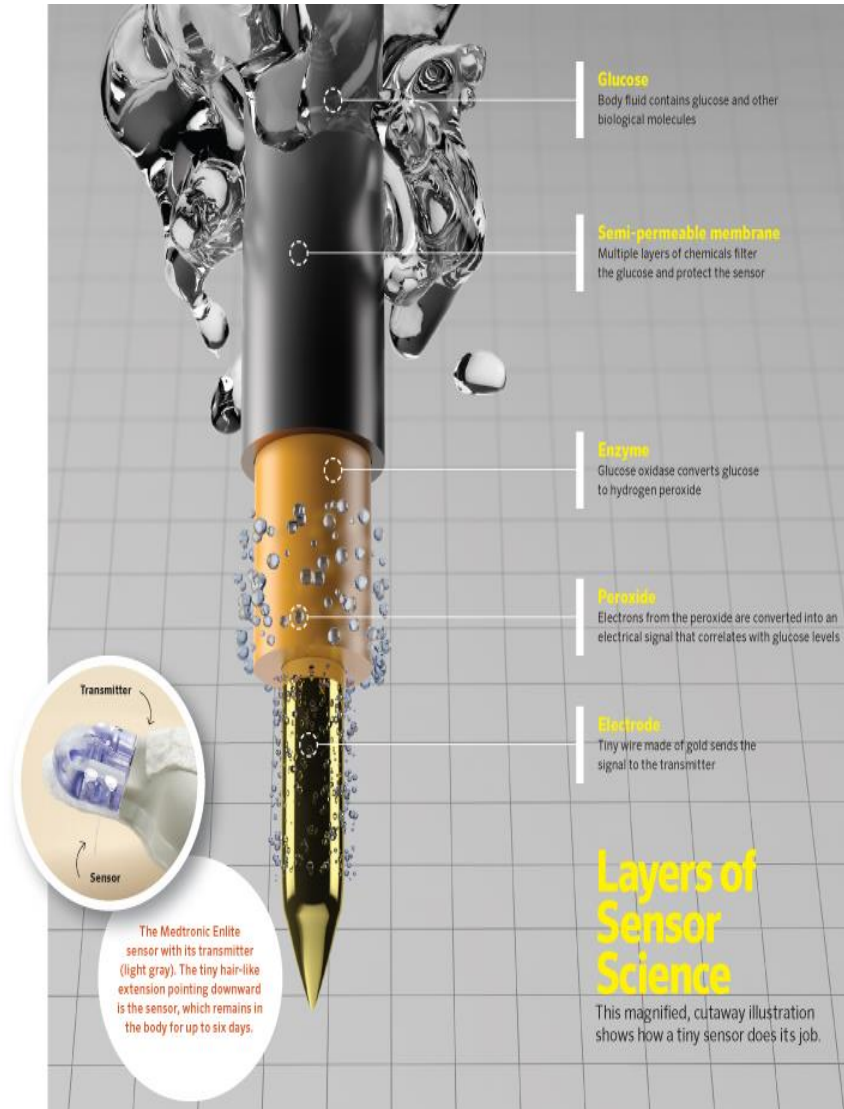


Glucose in the interstitial fluid hits the sensor causing a glucose – oxidation reaction to occur

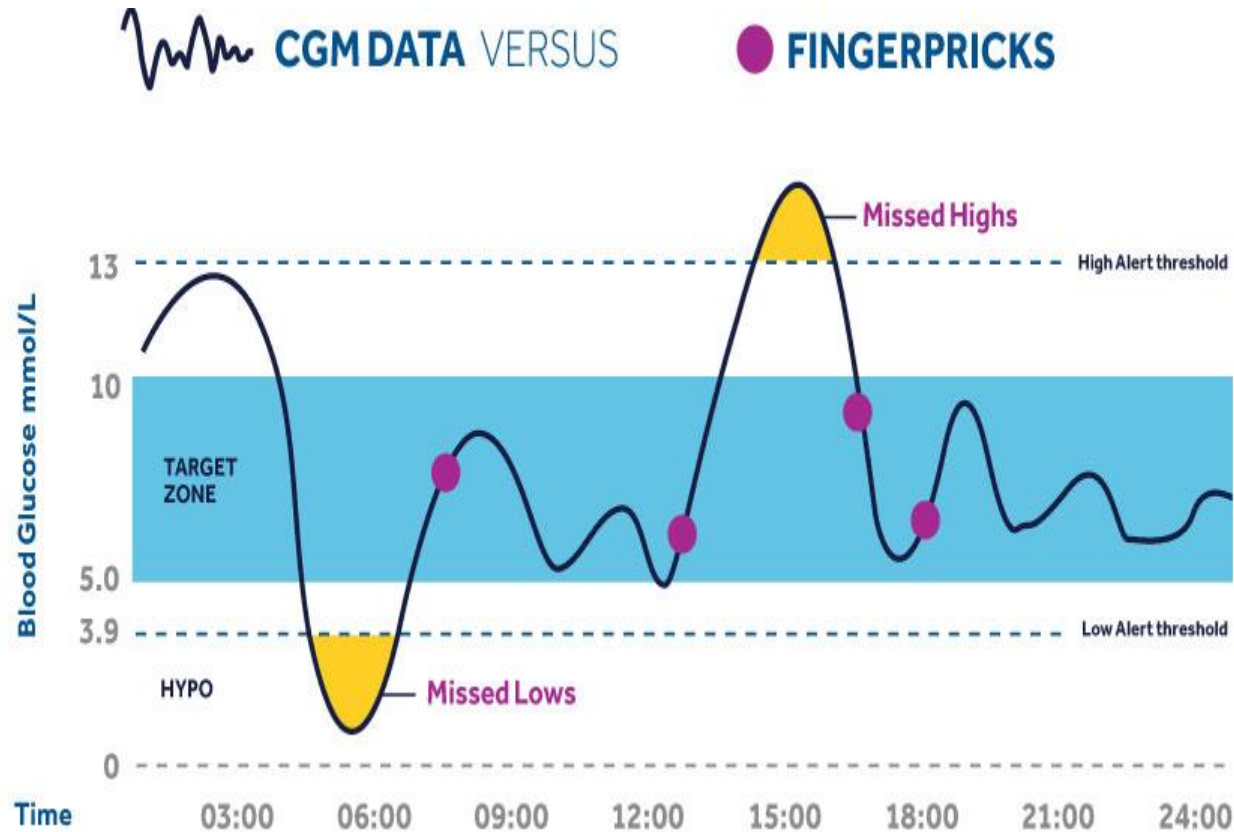
CGM technology

- **CGM estimates BG by measuring the concentration of glucose in the Interstitial Fluid (ISF)**
- **Signals from the ISF are calibrated to the fingerstick BG level**
- **The delay between the BG and the CGM is:**

Lag between ISF and BG + Electrochemical sensor delay

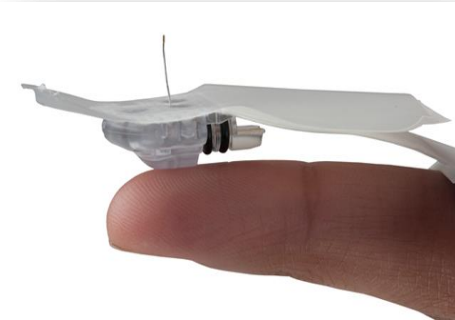


Why do a CGM ?



**Having this context helps CGM users manage glucose highs and lows, gives added insight into impacts that meals, exercise and illness may have on blood glucose levels
CGM can also contribute to better diabetes management**

Continuous Glucose Monitoring



Subcutaneous sensor reads interstitial fluid glucose every few minutes

Attached transmitter sends values to receiver



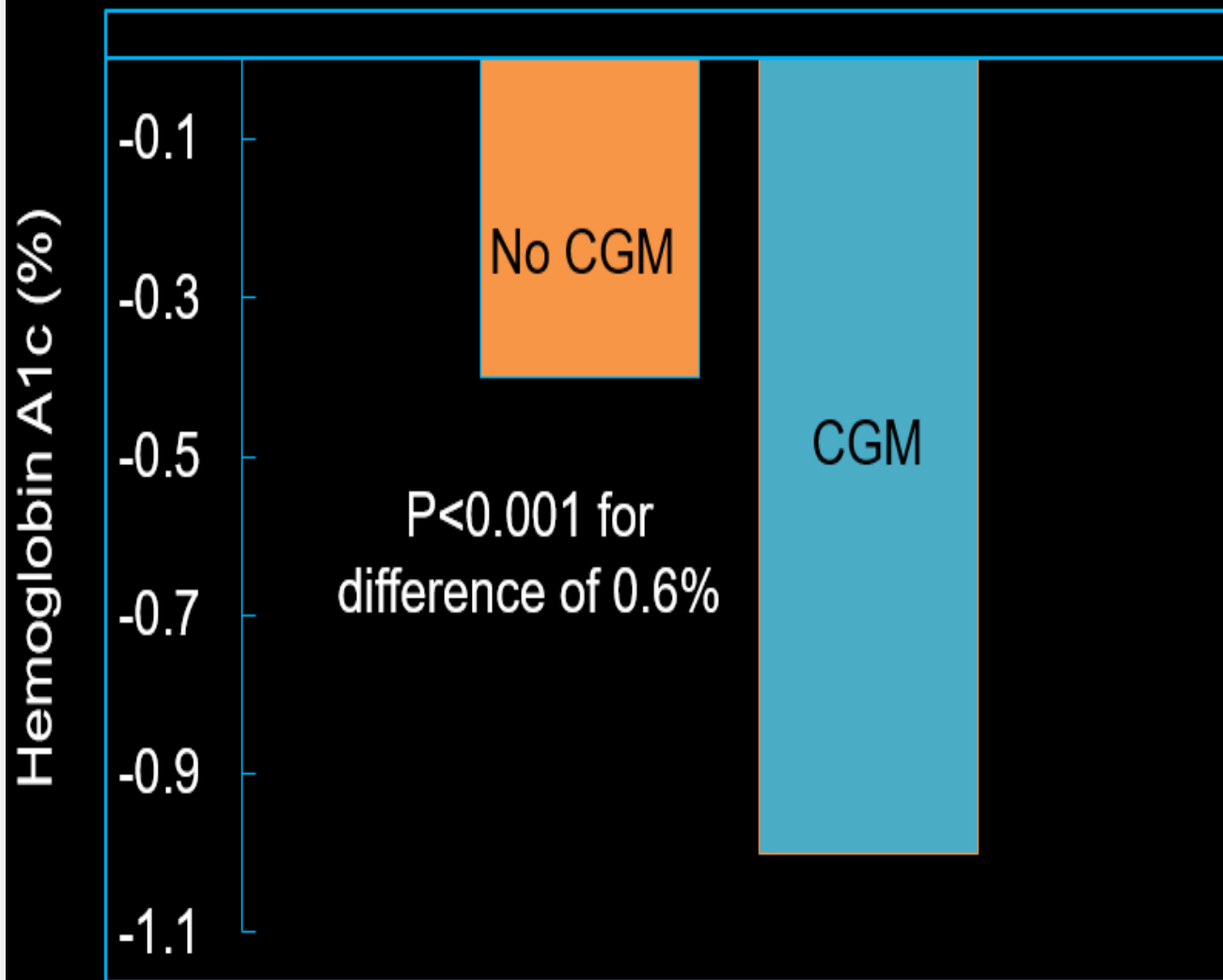
Receiver displays glucose values in real time and provides trend arrows

Trend arrows show how quickly glucose is changing

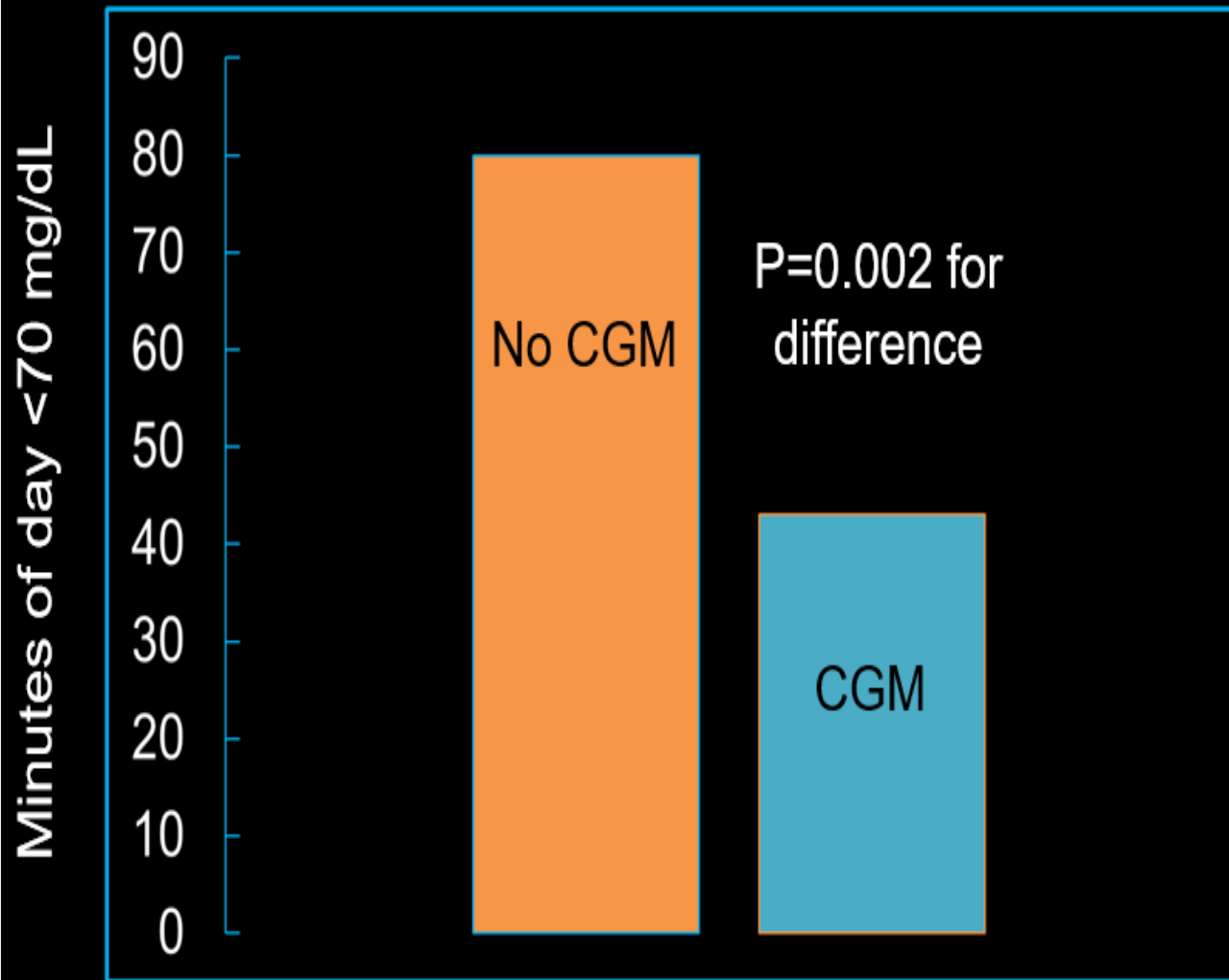


Sensor is changed by patient every 6-7 days

Greater A1c reduction at 24 weeks with CGM



Hypoglycemic time cut in half with CGM use



Drawbacks of CGM

Not a replacement to BGM!!!!

➤ **Issues related to**

- **Expensive in Indian context**
- **Accuracy**
- **Comfort**
- **Convenience**
- **Patient acceptance**

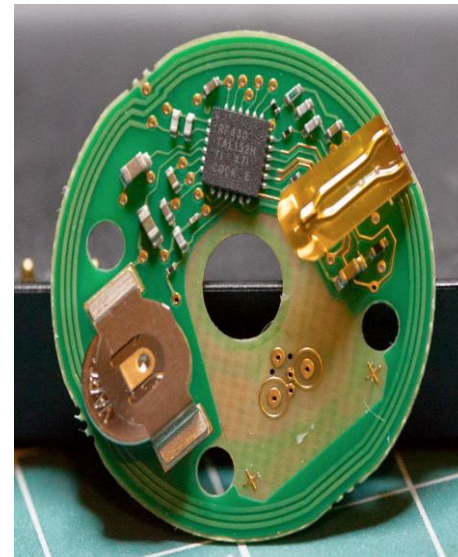
➤ **Most devices require frequent calibration**

Flash Glucose Monitoring

- **Measures plasma glucose in interstitial fluid**
- **BG values displayed when sensor is flashed with a reader device on demand**
- **Displays plot profile of last 8 hours**
- **Sensor can be worn for 14 days**
- **Has been shown to decrease time spent in hypoglycemia in type 1 and type 2 diabetes**

FGM-Free Style Libre

- Pro approved in the US
- CGM standard in Europe
- 14 day use, factory calibrated
- 10 day use in the US with 12 hour warm up
- Touch screen reader device
- Real time glucose value, CGM on-demand
- Captures and stores readings



SMBG/CGM/FGM

COMPARISON OF THE TECHNOLOGY

SMBG



- The BG meters work on electrochemistry, colorimetry or photometry¹
- The strips are biosensors, mostly based glucose oxidase/hexokinase enzyme¹
- Measure capillary blood glucose
- Measures spot glucose values
- Built-in memory
- Downloadable software/mobile app

CGM



- CGM sensors work on electrochemistry
- Glucose oxidase enzyme technology
- Measures glucose from interstitial fluid
- Measures glucose values continuously for 6 days
- Measure glucose every 5 mins (288 readings/day)
- Available as professional & personal systems
- Comprehensive reporting of trends & patterns

FGM



- FGM sensors work on electrochemistry
- Glucose oxidase enzyme technology
- Measures glucose from interstitial fluid
- Measures glucose values continuously for 14 days
- Measure glucose every 15 mins (90 readings/day)
- Available as professional system
- Comprehensive reporting of trends & patterns

	Blood glucose monitoring	Flash glucose monitoring	Continuous glucose monitoring	CGM with an insulin pump
Frequency of glucose readings	Dependent upon how often the person pricks their finger.	Dependent on how often the sensor is scanned. Device automatically samples interstitial glucose every 15 minutes and stores in memory for 8 hours.	CGM automatically samples interstitial glucose every 5 minutes and shows readings on a graph.	CGM automatically samples interstitial glucose every 5 minutes and shows readings on a graph on the insulin pump.
Glucose trends shown	No. Some meters can show patterns if glucose checks are done at the same time over several days.	Yes. When sensor is scanned, transmitter displays past 8 hours of glucose levels.	Yes.	Yes.
Memory	Varies depending on meter chosen.	Device stores readings from the past 8 hours.	Device displays and stores up to 24 hours of glucose readings.	Device displays and stores up to 24 hours of glucose readings.
Time taken for glucose check	1-2 minutes. Varies depending on meter.	Scan takes 1 second. Inserting sensor takes a few minutes.	Data viewed on demand on smart device, receiver or insulin pump.	Data viewed on demand on insulin pump.
Alarms	No. Alerts (not alarms) can be shown on smart devices for low and high blood glucose levels.	No. Alerts (not alarms) are shown on device but only if scan is done at a time when glucose is low or high.	Yes. Devices can be programmed to alarm for low and high glucose levels.	Yes. Devices can be programmed to alarm for low and high glucose levels.
Body part used for sampling	Tips or sides of fingers.	Approved for use on upper arm.	Approved for use on stomach.	Approved for use on stomach.
Calibration	Some meters need intermittent calibration using a solution.	Not needed.	Finger prick calibration needed at least twice daily.	Finger prick calibration needed at least twice daily.

SMBG/CGM/FGM

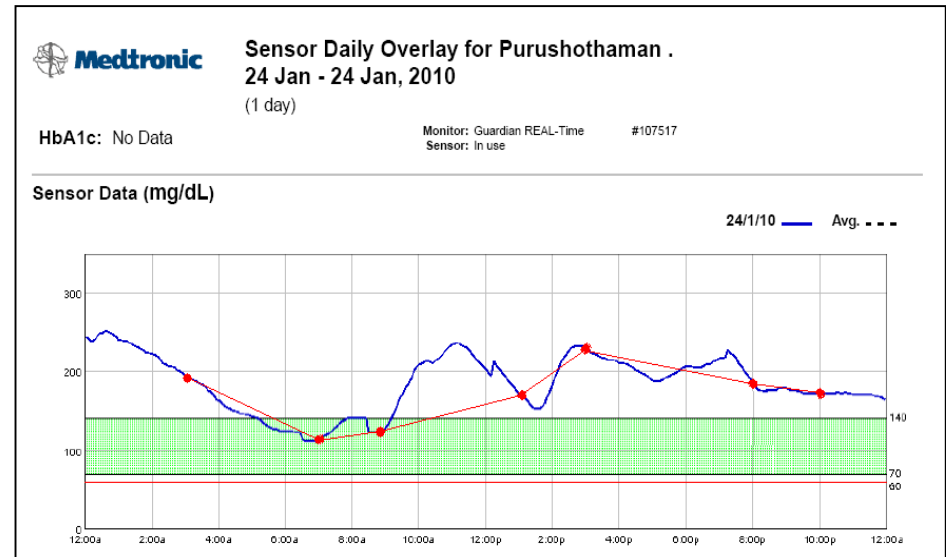
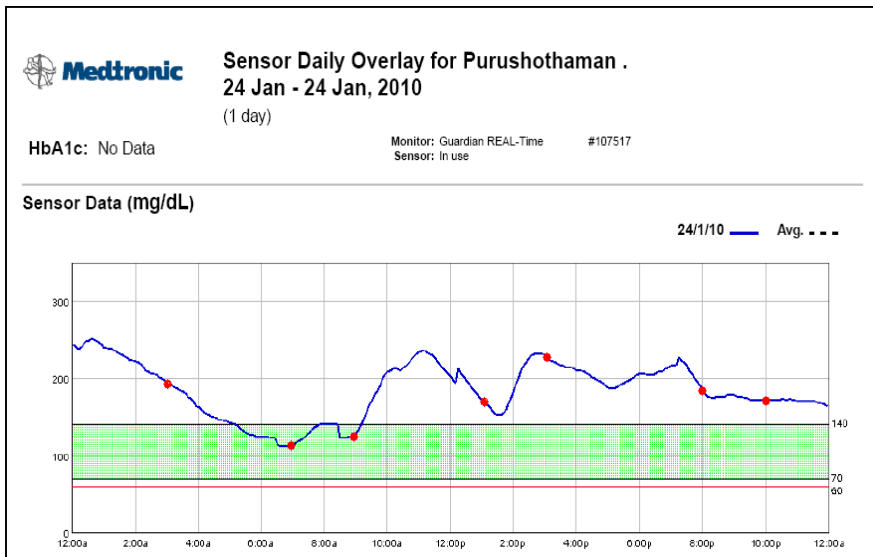
Features	SMBG	CGM	FGM
Time since being used	Time tested	Relatively new (approximately 15 years)	Very new (approximately 2 years)
Costs involved	Cheaper	Relatively expensive	Relatively cheaper
Accuracy	Very accurate	Better with newer sensors	Relatively accurate
Source of glucose measurement	Blood	ISF	ISF
Requirement of finger pricks	Always required	Required for calibration	Not required and hence virtually painless
Need of the device being attached to the body	No device attached to the body	Relatively big sensor attached to the body	Tiny sensor but still attached to the body
Volume of glucose data obtained	Provides a single glucose reading	Provides the glucose trend over several days (gives reading every 5 min for 5-7 days)	In addition to CGM, provides an AGP (gives reading every 15 min for 14 days)
Possible to access GV	Difficult	Yes	Yes
Level of motivation required	High	Moderate	Minimal
Level of subject interference required	Maximal	Moderate	Minimal and hence can capture glucose values of even those subjects who are not at all motivated

CASE STUDY

7 POINT SMBG VS CGM

Overlay 7 point SMBG over CGM graph

Connect the SMBG values to get the trend



What do we miss?

CASE STUDY

7 POINT SMBG VS CGM



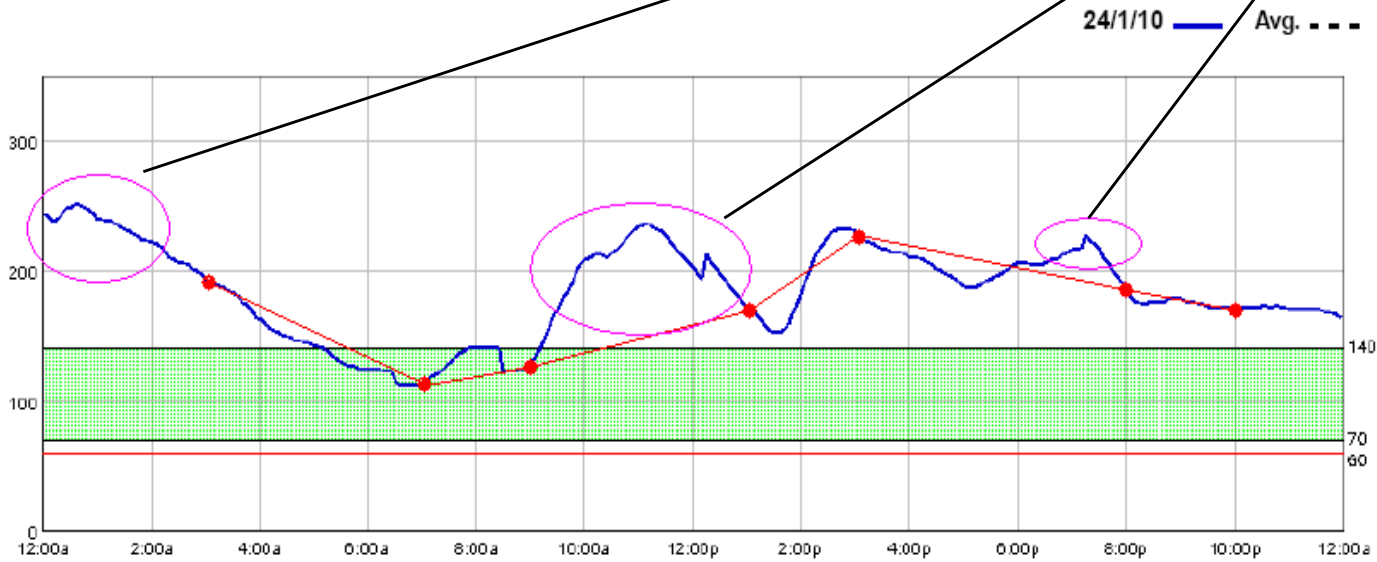
Sensor Daily Overlay for Purushothaman .
24 Jan - 24 Jan, 2010
(1 day)

HbA1c: No Data

Monitor: Guardian REAL-Time #107517
Sensor: In use

7 point SMBG
can miss
excursions

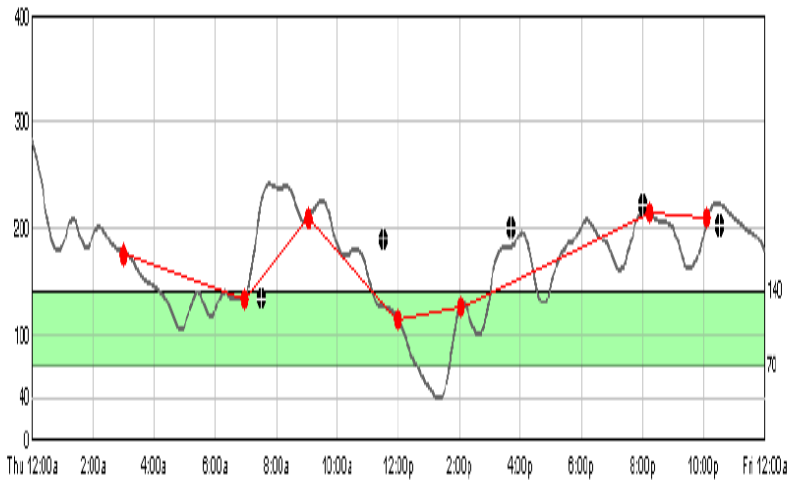
Sensor Data (mg/dL)



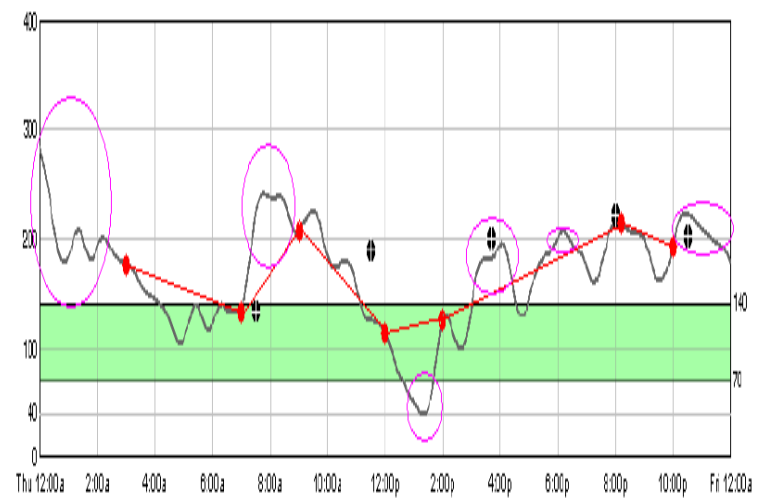
CASE STUDY

7 POINT SMBG VS CGM

Thu 30 Sep (mg/dL) Sensor Use Clinical Judgement



Thu 30 Sep (mg/dL) Sensor Use Clinical Judgement



CASE STUDY

7 POINT SMBG VS CGM



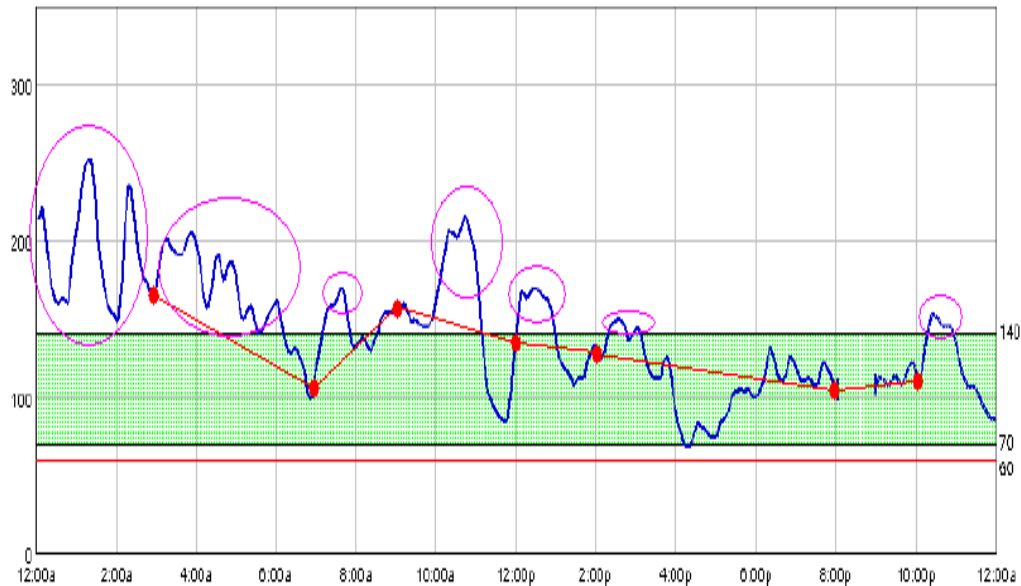
Sensor Daily Overlay for Esta Paul
23 Apr - 23 Apr, 2010
(1 day)

HbA1c: No Data

Monitor: Guardian REAL-Time #107529
Sensor: In use

Sensor Data (mg/dL)

23/4/10 — Avg. ...



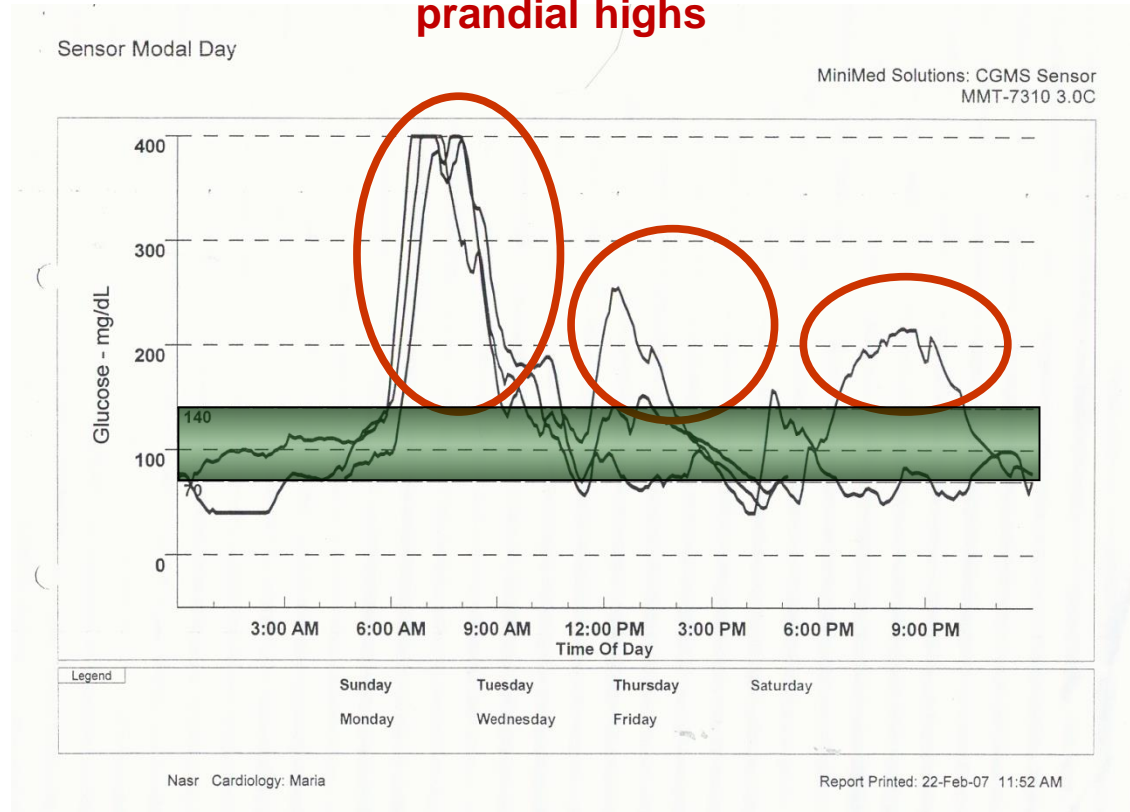
CASE STUDY

Three critical areas meter readings often miss:

WHAT DOES SMBG MISS?

- 60 year old patient with type 1 diabetes
 - A1C = 8.5%
 - Fingersticks were checked before breakfast and were in the 80-90 range
 - Fingersticks prior to meals were also in the 100s
- Nocturnal glucose control
 - Asymptomatic hypoglycemia
 - Post-prandial glucose excursions

Shows that high glucose average is from post-prandial highs

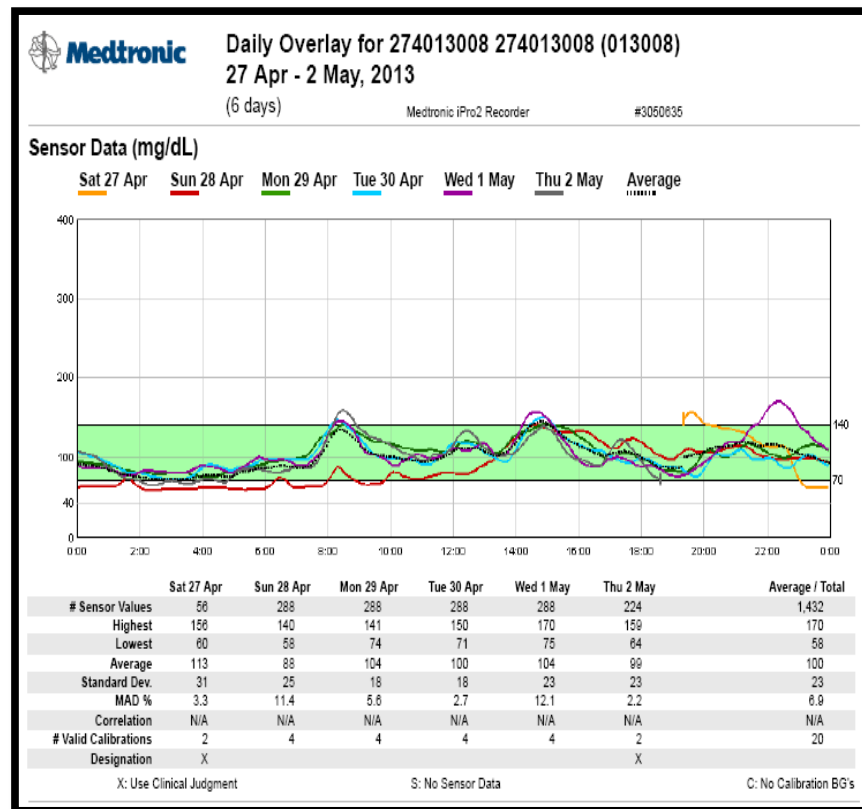
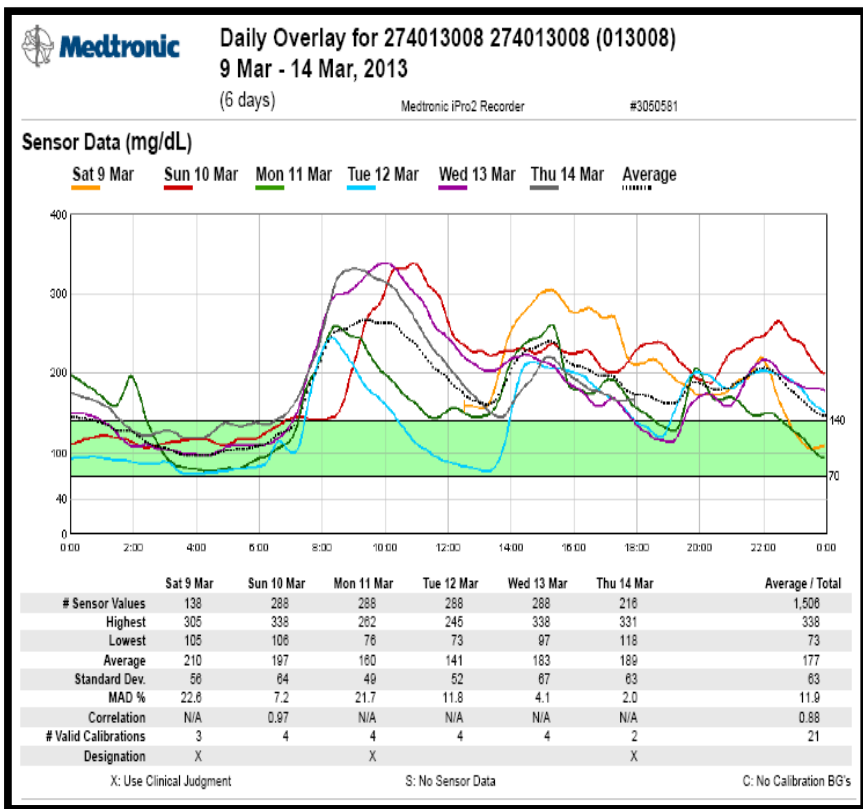


CASE STUDY

CGMS-A THERAPY OPTIMIZER

Baseline CGM Graph

Post treatment CGM Graph



Mohan et al. Use of Retrospective CGM For Optimizing Management of Type 2 Diabetes in India; Journal of the Association of Physicians of India, volume 64, April 2016

ORIGINAL ARTICLE



Use of Ambulatory Glucose Profile for Improving Monitoring and Management of T2DM

Banshi Saboo¹, Shruti V Sheth¹, Shashank Joshi², Sudhir Bhandari³, Jothydev Kesavadev⁴, Anuj Maheshwari⁵, Manish Agrawal¹, Dhruvi Hasnani¹, Feny Patel¹, Dharmendra Panchal¹, Rutul Goklani¹

Abstract

Aim: To demonstrate glycemic variability in type 2 diabetic patients and consequent control of the same.

Methods: 108 patients with type 2 diabetes with an HbA1c level of 7.5-8.5% were selected for the study. A Freestyle Libre Pro AGP sensor was applied to the patients after explaining the patient about the same. Next, they were called for follow up at 3rd, 7th, 11th and 14th days. Based on the readings and graph obtained, diet and treatment changes were made on various follow-up days. The sensor was removed at the end of 14 days.

Results: Out of the 108 subjects, 106 completed the study. There were no adverse device effects. 98 patients had therapy changes while the rest had diet and lifestyle modifications. The mean HbA1c decreased from 7.96% to 7.03% by the end of 15 days. The glycemic variability curves helped in recognizing and treating masked or asymptomatic hypoglycemic events. It also graphically shows intervals of optimal and sub-optimal glycemia.

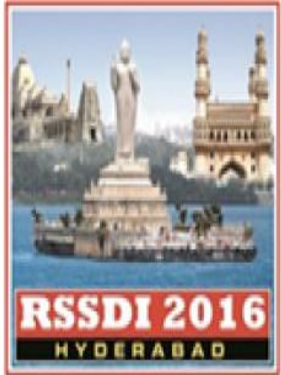
Conclusion: AGP is one of the most recent, innovative developments that are being used to monitor Glycaemic variability in DM patients. AGP is generated from the Flash Glucose Monitoring device which is like a CGM device attached to the patient for a maximum period of 14 days, which checks the ISF glucose at every 15 minutes. We are able to get a Glycaemic variability curve, a median, a modal, various percentiles and statistical data generated through this.

AGP study in the patient provides the doctor with an opportunity to have a complete glycemic picture of the patient. It offers a reliable, predictive, standardized visualization of the glucose data. We were able to not only reduce the Glycaemic variability but were also able to improve their Quality of Life by reducing the frequency of hypos. The data lead to breaking of the clinical inertia and provided a valuable insight into Glycaemic patterns. The achievement of near to normal Glycaemic status at the end of 14 days reflected the use of AGP as an interventional tool.

- 1 AGP study in the patient provides the doctor with an opportunity to have a complete glycemic picture of the patient. It offers a reliable, predictive, standardized visualization of the glucose data. We were able to not only reduce
- 3 the Glycaemic variability but were also able to improve their Quality of Life by reducing the frequency of hypos. The data lead to breaking of the clinical inertia
- 4 and provided a valuable insight into Glycaemic patterns. The achievement of near to normal Glycaemic status at the end of 14 days reflected the use of AGP as an interventional tool.

2

5



44th Annual Conference of Research Society for The Study of Diabetes in India

18 -20 November 2016

Hyderabad International Convention Centre (HICC), Hyderabad, Telangana, India

POSTER TITLE: Ambulatory Glucose Profile - A Convenient Tool for Therapeutic Decision Making in Diabetes (Abstract ID 44)

PRESENTER NAME: Dr Vishal Kastwar*, MD

* Director, Shreedeeep Medical Care Centre, Jabalpur, MP

AGP Utilisation in India

Glycemic Variability during Pregnancy can be detected by
Ambulatory Glucose Profile using Freestyle Libre Pro
Bhavana Sosale*, Aravind R Sosale**

*MBBS,MD, **MBBS, DNB, FRCP (Glasgow and Edinburgh), Diacon Hospital, Bangalore, India



Managing Hypoglycemia through the Novel Flash Glucose Monitoring System in Indian Diabetics

Author Block: YASHPAL MUNJAL, ANUPAM PRAKASH, GHANSHYAM PANGTEY, NAVNEET WADHWA, *Delhi, India, Mumbai, India*



Use of ambulatory glucose profile (AGP) for
prevention and treatment of diabetic nephropathy



Dr. Mita Shah, Dr. Prashant Rajput, Dr. Zaheer Yirani, Dr. Hepal Vora, Dr. Shreekant Adate, Dr. Nitin Deote, Dr. Bharat Shah
Institute of Renal Sciences, Global Hospital, Mumbai

Different patient scenarios for CGM use in Indian patients

- A1C that does not match SMBG
- Elevated A1C
- Noncompliant patients
- Therapy adjustment
- Insulin adjustment
- High glucose variability
- Hypoglycemia patterns
- Hyperglycemia patterns
- Baseline assessment

Managing diabetes without CGM can feel like walking a tightrope with a blindfold on



International Consensus available on CGM

Diabetes Care Volume 40, December 2017



International Consensus on Use of Continuous Glucose Monitoring

Diabetes Care 2017;40:1631–1640 | <https://doi.org/10.2337/dc17-1600>

Continuous Glucose Monitoring: Evidence and Consensus Statement for Clinical Use

Andreas Liebl, M.D.,¹ Helmut R. Henrichs, M.D.,² Lutz Heinemann, Ph.D.,³
Guido Freckmann, M.D.,⁴ Eberhard Biermann, M.D.,⁵ and Andreas Thomas, Ph.D.,⁶
for the Continuous Glucose Monitoring Working Group of the
Working Group Diabetes Technology of the German Diabetes Association

See discussions, stats, and author profiles for this publication at: <https://www.researchgate.net/publication/326882978>

2018 ISPAD Clinical Practice Consensus Guidelines MANAGEMENT AND SUPPORT OF CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES IN SCHOOL

Article in *Pediatric Diabetes* · August 2018

DOI: 10.1111/pedi.12743

**2017: ATTD, EASD and ADA
Consensus Recommends
AGP as Standard Report**

International Consensus on use of CGM

International Consensus on Use of Continuous Glucose Monitoring

Diabetes Care 2017;40:1631–1640 | <https://doi.org/10.2337/dc17-1600>

**2017: ATTD, EASD and ADA
Consensus Recommends
AGP as Standard Report**

Achieving Guidelines on CGM Use

- **International meeting before ATTD conference in Feb 2017 to make recommendations for appropriate use and interpretation of CGM**
- **“CGM should be considered in conjunction with HbA1c for glycemic status assessment and therapy adjustment in all patients with type 1 diabetes and patients with type 2 diabetes treated with intensive insulin therapy who are not achieving glucose targets, especially if the patient is experiencing problematic hypoglycemia”**

International Consensus on Use of Continuous Glucose Monitoring

Diabetes Care 2017;40:1631–1640 | <https://doi.org/10.2337/dc17-1600>

Measurement of glycated hemoglobin (HbA_{1c}) has been the traditional method for assessing glycemic control. However, it does not reflect intra- and interday glycemic excursions that may lead to acute events (such as hypoglycemia) or postprandial hyperglycemia, which have been linked to both microvascular and macrovascular complications. Continuous glucose monitoring (CGM), either from real-time use (rtCGM) or intermittently viewed (iCGM), addresses many of the limitations inherent in HbA_{1c} testing and self-monitoring of blood glucose. Although both provide the means to move beyond the HbA_{1c} measurement as the sole marker of glycemic control, standardized metrics for analyzing CGM data are lacking. Moreover, clear criteria for matching people with diabetes to the most appropriate glucose monitoring methodologies, as

Thomas Danne,¹ Revital Nimri,²
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William V. Tamborlane,²⁹
Stuart A. Weinzimer,²⁹ and Moshe Phillip²

¹Diabetes Centre for Children and Adolescents, Children's and Youth Hospital "Auf Der Bult," Hannover, Germany

²The Myrtle and Henry Hirsch National Center for Child and Adolescent Diabetes and Endocrinology

Indian perspective

Latest

Consensus Guidelines

Consensus and Recommendations on Continuous Glucose Monitoring

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Patient-Centered Care

Ask the patient:

What is important to you?

What are your goals?
Health and life goals?

Identify and respect:

Differences

Values

Preferences

Expressed needs

Decision making must be mutually attained

Patients **MUST** be listened to and not dictated to

Patient has a say in care plan

Patient chooses therapy and device after being presented all options

KEY TAKE AWAYS

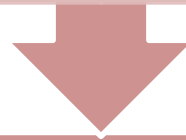
- **SMBG is relatively inexpensive, easy to train, provides an accurate measure of capillary glucose concentrations**
- **SMBG provides snap-shots of blood glucose concentration**
- **CGM provides a near-continuous read-out of interstitial glucose concentration, which adequately reflects blood glucose concentration and can help to identify trends and patterns in glucose**
- **CGM can be programmed to give alarms for highs or lows, allowing patients to treat these abnormal values**

Planning Care for People with Diabetes

Consider all options:

Continuous Glucose Monitoring

**Blood Glucose Monitoring with
Glucometers**



Consider Possible Payer Barriers



Present All Options to Patient: Explore Pros and Cons Together

Give the patient the power to choose



**Thank
you!**

