

Improved Metabolic Control in Diabetic Patients using the CGMS

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내용

1. 정의와 사용이유
2. 종류와 특징
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5. 핵심메시지



CGMS

환자의 질문은 계속된다...

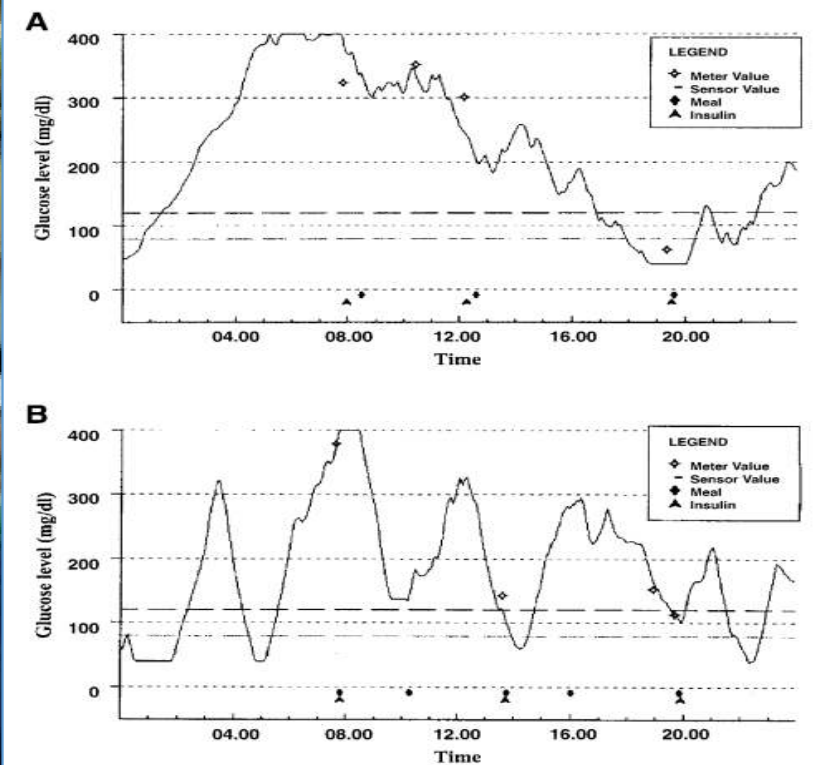


Figure 2—An example of a prolonged hyperglycemic period in a 15-year-old girl with $HbA_{1c} = 9.1\%$ (A) and rapid glycaemic excursions in a 12.5-year-old boy with $HbA_{1c} = 7.5\%$ (B).

Continuous Glucose Monitoring System

10 sec.

5 min.

288/day

3~6 days

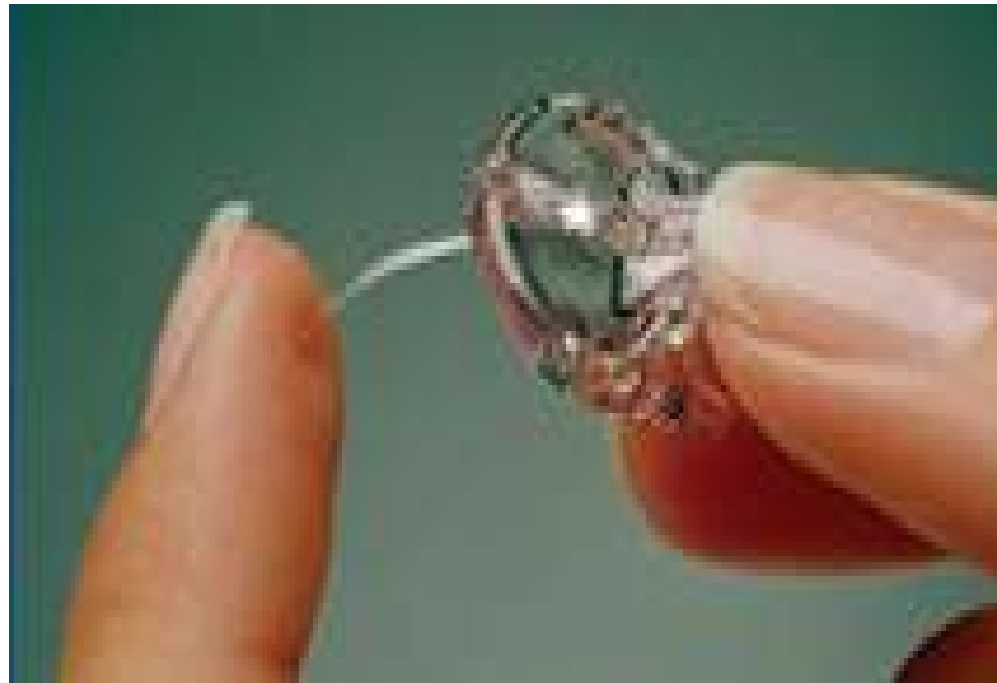




Figure 2—An example of a prolonged hyperglycemia (>180 mg/dl) in 9.1% (A) and rapid glycemic excursions in

CGMS RECOMMENDATIONS

ADA 2013

Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1c in selected adults (aged ≥ 25 years) with type 1 diabetes. (A).

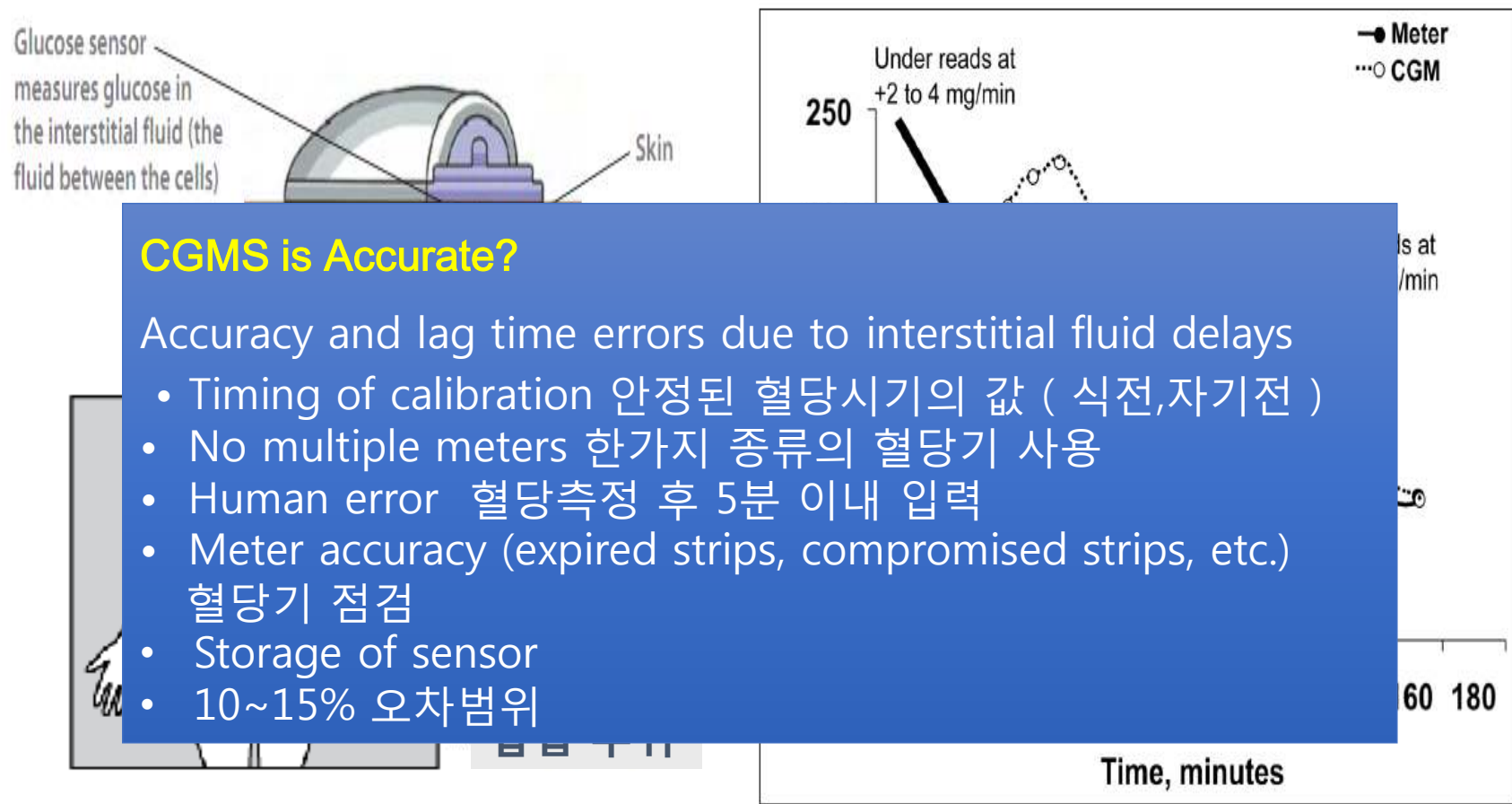
AACE 2010

Personal devices can be used for glucose control and prevention of hypoglycemia in patients with type 1 diabetes and pregnancy with diabetes.

CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes(E)

KDA 2013

혈당의 변동폭이 크거나 저혈당이 빈번한 경우에 혈당조절을 감시하는 방법으로 지속적 혈당 측정기기를 사용할 수도 있다. [E]



CGMS is Accurate?

Accuracy and lag time errors due to interstitial fluid delays

- Timing of calibration 안정된 혈당시기의 값 (식전,자기전)
- No multiple meters 한가지 종류의 혈당기 사용
- Human error 혈당측정 후 5분 이내 입력
- Meter accuracy (expired strips, compromised strips, etc.)
혈당기 점검
- Storage of sensor
- 10~15% 오차범위

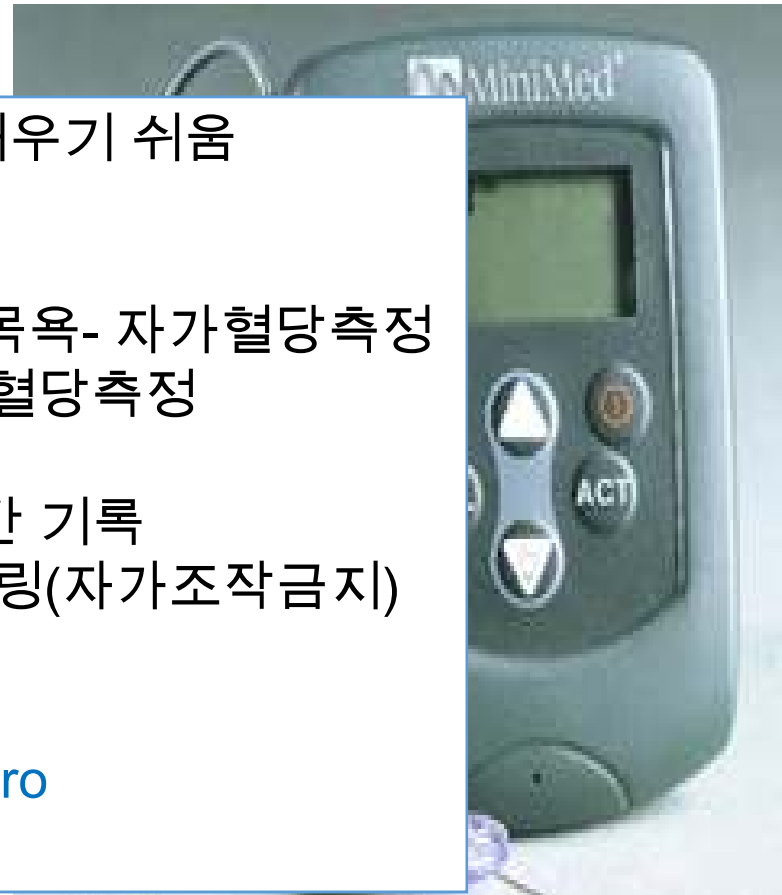
- ❖ **Physiologic lag** : 5 to 10 minutes, Especially undergoing rapid change
- ❖ **Calibration of sensor** (SMBG and enter glycemic values into the CGMS monitor) is essential when blood glucose levels are stable.

Professional CGM "Gold" = Retrospective CGM

- ❖ 병원소
- ❖ Maski
- 데이터
- 의료진
- ❖ Bias 업
- ❖ No ale
- (hyp

- ✓ 교육시간이 짧고 환자도 배우기 쉬움
- ✓ 과정
처방- 동의(가격 등)-미리 목욕- 자가혈당측정
과 입력방법-CAL Error시 혈당측정
- ✓ 식사, 운동, 인슐린주사시간 기록
Cable 주의, 최소한의 핸들링(자가조작금지)

→ 단종, 차후 Medtronic iPro



1999 FDA, USA -> 2002, 국내승인

CGMS[®] System Components



Monitor(모니터)



Sensor (센서:72시간사용)



Sen -serter[®]:

서터: 통증감소시키는 센서주입보조기



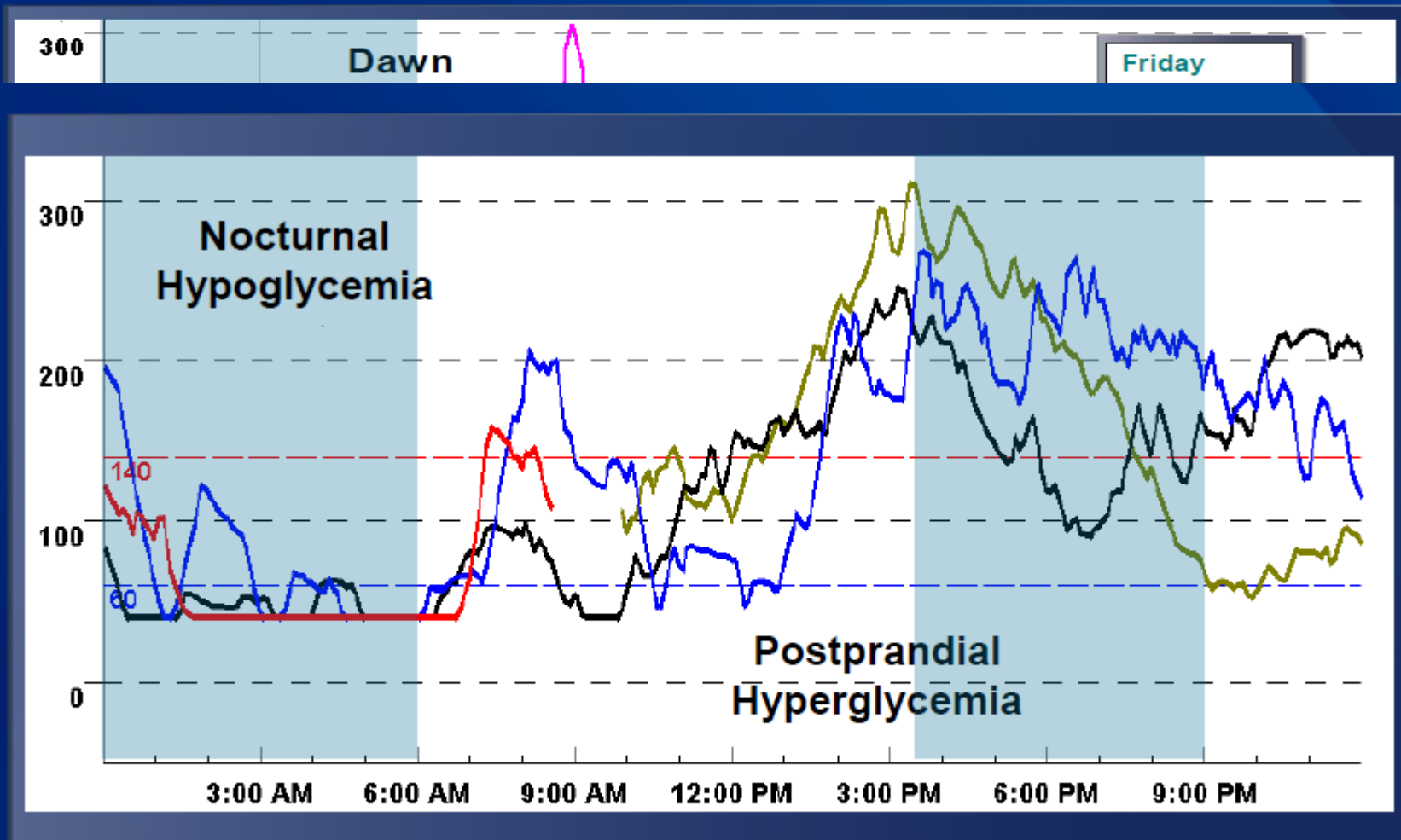
Download Software and Com-Station(컴스테이션:컴퓨터 다운로드시 사용)



Test Plug

(검사플러그:모니터 이상 시 점검)

Modal Day Summary Report: Case Study



Personal CGM Guardian Real Time

- ❖ 환자나 병원 소유
- ❖ 계속적으로 혈당치가 보여짐으로써 즉각적인 치료적 조정이 실시간으로 가능



혈당조절에 대한 열의
저혈당 없이 혈당을 철저하게 잘 조절하려는 환자
HbA1c가 7% 이내의 동기부여가 매우 잘되는 제1형
당뇨병을 가진 초등학생이나 청소년
영문으로 나타나는 여러 가지 표시들을 해독하고 적절한
대처를 할 수 있고 Alarm이 울리는 것도 바로
알아차려야 하기 때문에 시각, 청각에 장애가 없는 환자

인슐린펌프+ CGM

MiniMed Paradigm Real-Time

MiniLink
transmitter and sensor

Insulin Pump +
Guardian Real Time



Figure 1a



종류
Personal CGM

Abbott Freestyle
Navigator

Figure 1b



DexCom
Seven Plus

Figure 1c



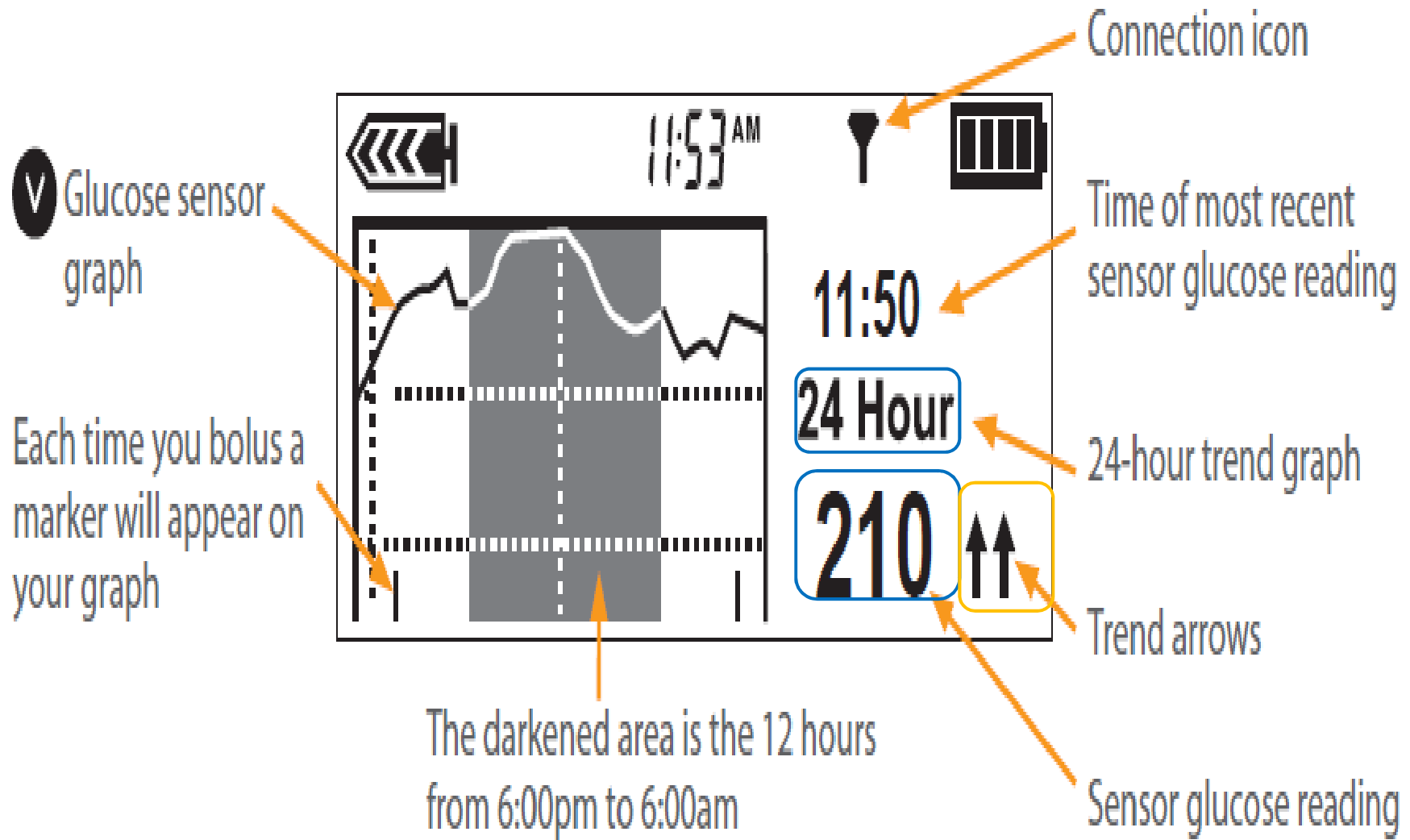
Medtronic Guardian
REAL-Time

Figure 1d

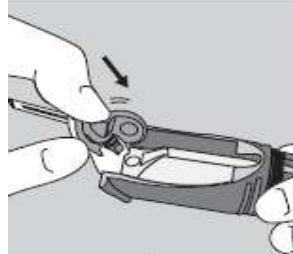


MiniMed Paradigm REAL-Time
Revel System

Personal CGM



Insertion:



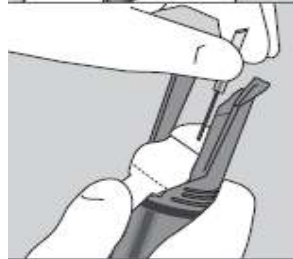
1 Place the glucose sensor in the Sen-serter Insertion Device.



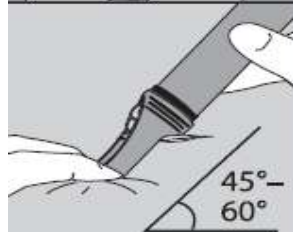
2 Place your fingers on the white button of the Sen-serter Insertion Device and gently slide it away from the glucose sensor in a horizontal motion.



3 While holding the Sen-serter Insertion Device, gently hold the glucose sensor in place and remove the white paper from the adhesive pad. Press adhesive against your skin.



4 Gently hold the glucose sensor base with two fingers and gently remove the introducer needle at the same angle that it was inserted.



5 Insert the Sen-serter Insertion Device on the skin at a 45-60° angle. Fit it slightly up to achieve a 60° insertion angle.



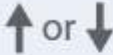
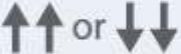


6 Hold the skin taut. Place two fingers on the Sen-serter base to stabilize it for insertion. Press the white button on top of the Sen-serter Insertion Device.

Gently hold the glucose sensor in place and gently slide the Sen-serter Insertion Device away from the glucose sensor in a horizontal motion.

Gently hold the glucose sensor in place and remove the white paper from the adhesive pad. Press adhesive against your skin.

Gently hold the glucose sensor base with two fingers and gently remove the introducer needle at the same angle that it was inserted.

Wait 10-15 minutes before connecting the fully charged MiniLink® transmitter to the glucose sensor. Be sure to follow step 2 and 3 of this guide before connecting the MiniLink transmitter.

Alert	What It Means	How to Respond
Sensor End (SenEnd)	Sensor has been used for 72 hours.	Remove sensor and follow guide for new sensor start.
Sensor Error (SenErr)	Sensor signals are either too high or too low.	Clear the alert and ignore if this happens during initialization.
What the Sensor Icons Mean		
	Glucose has risen or fallen 1-2 mg/dL per minute.	
	Glucose has risen or fallen 2.0 or more mg/dL per minute.	
	Insulin pump indicates that the MiniLink® transmitter and insulin pump are communicating properly.	
	Pump has not received a signal for more than 5–7 minutes. This is okay; the MiniLink transmitter stores up to 40 minutes of data and will send these readings to the insulin pump once a signal is reestablished.	
High Predicted (PrdHi)	Sensor glucose is trending to reach or go above your high glucose limit in the length of time you selected for the high predictive alert.	Consider taking corrective action after confirming with a BG meter reading.
Low Predicted (PrdLow)	Sensor glucose is trending to reach or go below your low glucose limit in the length of time you selected for the low predictive alert.	Consider taking corrective action after confirming with a BG meter reading.

setting and/or **repeat** setting for this alert.

사용시 주의점

Not Water Proof

X-rays, MRIs and CT scans

If you are going to have an X-ray, CT scan, MRI or other type of exposure to radiation, take off your insulin pump, BG meter, MiniLink transmitter and glucose sensor and remove them from the area.

keeping the cell phone at least 12 inches (31 cm) away from the receiving device, transmitter

Air Travel

The Federal Aviation Administration (FAA) requires that devices with radio frequency capabilities should not be used on an aircraft.



EVIDENCE SUPPORTING THE USE OF CGM

The Sensor-Augmented Pump Therapy for HbA1c Reduction (STAR-1) study

- ❖ 인슐린펌프+ SMBG only vs.
인슐린펌프+ SMBG + **personal CGM**.
- ❖ Primary end point: HbA_{1c} change
Evaluated hyperglycemia and/or hypoglycemia incidence
- ❖ 98 adults and 40 adolescents (12 to 72 years of age)

6-Month HbA1c (baseline HbA1c 8.44%)

CGM + SMBG-treated patients: 7.77%

SMBG patients: 7.84%

- ✓ HbA1c levels were similarly reduced in both groups.
- ✓ CGM device the least often and had the highest HbA1c levels.

1-2. JDRF(Adolescent & Adult)

The Juvenile Diabetes Research Foundation (JDRF) Sensor Study

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes

The Juvenile Diabetes Research Foundation Continuous Glucose
Monitoring Study Group*

Primary end point:

HbA_{1c} change from baseline

Hypoglycemia incidence

Evaluated patients 15 to 24 and ≥25 years of age (adult groups)

Table 2. Glycemic Outcomes at 26 Weeks, According to Age.*

Variable	≥25 Yr			15–24 Yr		
	Continuous-Monitoring Group (N=52)	Control Group (N=46)	P Value	Continuous-Monitoring Group (N=57)	Control Group (N=53)	P Value
	Glycated hemoglobin level†					
At baseline — %	7.6±0.5	7.6±0.5		8.0±0.7	7.9±0.8	
Change from baseline to 26 weeks — %‡	-0.50±0.56	0.02±0.45	<0.001	-0.18±0.65	-0.21±0.61	0.52
Relative decrease by ≥10% — no. (%)	13 (26)	2 (4)	0.003	8 (14)	5 (10)	0.46
Absolute decrease by ≥0.5% — no. (%)	2 (4)	1 (2)	0.17	2 (4)	1 (2)	0.7
Relative increase ≥10% — no. (%)	1 (2)	0 (0)	0.8	1 (2)	0 (0)	0.8
Absolute increase ≥0.5% — no. (%)	1 (2)	0 (0)	0.4	1 (2)	0 (0)	0.4
26-week level <7.0% — no. (%)	15 (30)	3 (7)	0.006	7 (13)	7 (14)	0.0
26-week level <7.0%, with no severe hypoglycemic events — no. (%)	15 (30)	3 (7)	0.006	7 (13)	7 (14)	0.67

Age Effect
 심각한 저혈당(-)
 센서 사용 빈도와 A1c 반비례

대상 8~14세 (YOUTH)

YOUTH	DirecNet	Two, 13-week pilot studies (DirecNet); randomized clinical trial (JDRF CGM) Primary end point: HbA _{1c} change	HbA _{1c} among CSII users improved from 7.1% at baseline to 6.8% at 13 weeks ^a Hypoglycemia frequency changed from 4.5% at baseline to 5.5% at 13 weeks ^b
	JDRF CGM 연장	Safety Hyp	성인보다 센서의 사용빈도는 적지만 자주 센서를 사용한 군에서 저혈당의 증가 없이 혈당이 향상되고 12개월까지 유지 Hypoglycemia rates did not differ between treatment groups

Key takeaway: Youth were much less likely than adults to use CGM devices on a near-daily basis; the best HbA_{1c}-lowering results were seen in patients who used the sensor 6 to 7 days a week

대상 임신부 (Pregnancy)

Table 2
Studies Evaluating the Efficacy of Professional Continuous Glucose Monitoring in Pregnant Women With Diabetes Mellitus^a (32-36)

Study	Goal	Patients	Duration	Intervention	Outcomes
Jovanović (2000) (32)	Evaluate professional CGM to detect previous unknown hyperglycemia in women with GDM	10 women with GDM (no gestational diabetes provided)	390 min/24 h		Mean total min/24 h previously undetected hyperglycemia: ~390 min
Yogev et al (2003) (33)	Comparison of daily glycemic profiles in pregnant women with type 1 DM measured by professional CGM vs intermittent glucose monitoring	34 pregnant women with <u>type 1 DM</u> , gestational age 16 to 32 weeks receiving multiple insulin injections	72 hours	Professional CGM performed 6 to 8 times a day	Average of 780 ± 54 glucose measurements recorded for CGM patients; mean total hyperglycemia in professional CGM arm (undetected by fingerstick): 192 ± 28 min/24 h; nocturnal hypoglycemic events recorded in a total of 26 patients

Study	Goal	Patients	Duration	Intervention	Outcomes
Chen et al (2003) (34)	Evaluate daily glucose level in pregnant women with GDM using professional	57 women with GDM, gestational age 24 to 35 weeks; 23 treated	30 days	Professional CGM vs SMBG with fingerstick	Average of 763 ± 62 glucose measurements recorded for CGM patients; mean total hyperglycemia (undetected by fingerstick): 132 ± 31 min/24 h in insulin-treated group and 94 ± 23 min/24 h in diet-treated group; 14 patients, all insulin-treated, experienced nocturnal hypoglycemia

Gestation (weeks)	Standard antenatal care (n=33)	Antenatal care plus continuous glucose monitoring (n=38)
8	7.5	7.2
12	7.0	6.8
16	6.5	6.4
20	6.2	6.1
24	6.2	6.1
28	6.3	6.2
32	6.4	6.1
36	6.4	5.8

Fig 2 | Mean HbA_{1c} levels every four weeks in women receiving standard antenatal care (n=33) or antenatal care plus continuous glucose monitoring (n=38). Vertical lines are standard deviation at each time point

Patients using professional CGM had lower mean hemoglobin A_{1c} levels (5.8% vs 6.4%); infants of CGM-using women had decreased median birth weight percentiles (69% vs 93%) and a reduced risk of macrosomia (odds ratio 0.36; 95% CI, 0.13-0.98; P = .05)



available at www.sciencedirect.com

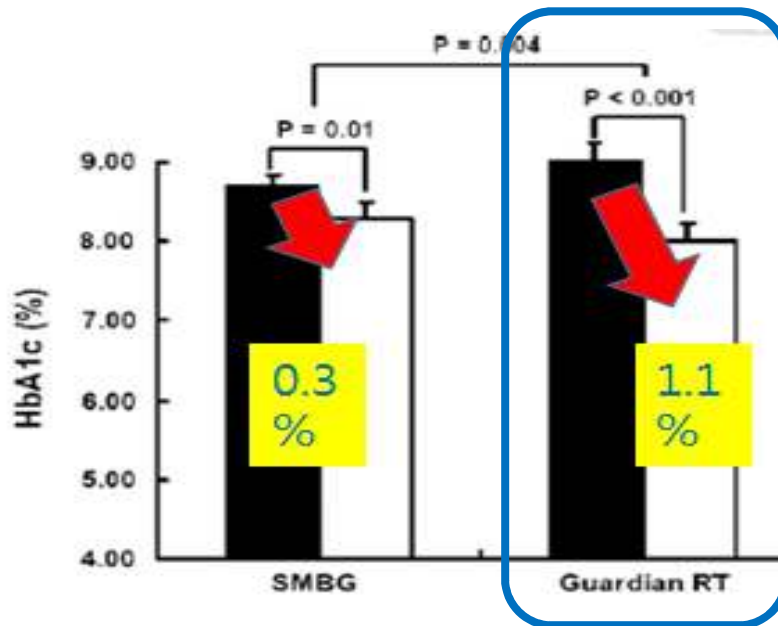


journal homepage: www.elsevier.com/locate/diabres

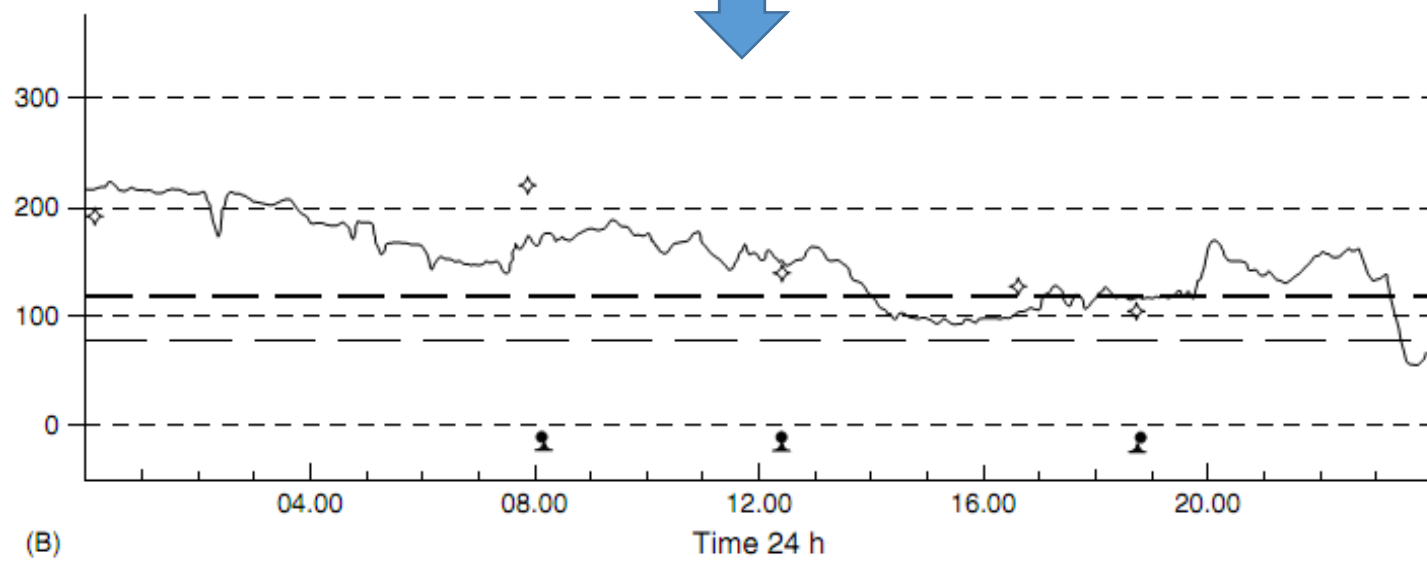
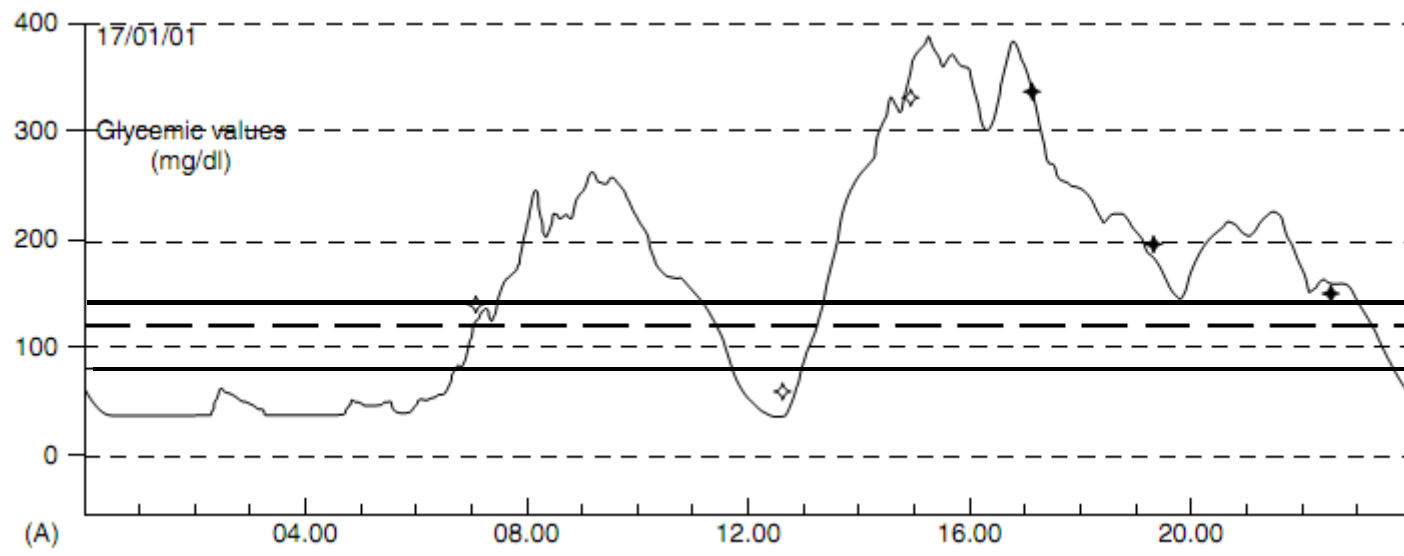


International Diabetes Federation

Use of a real time continuous glucose monitoring system as a motivational device for poorly controlled type 2 diabetes



- RT-CGM 그룹에서 하루 총칼로리 섭취량, 체중 감소량이 유의하게 감소되었다.
- RT-CGM 그룹에서 일주일 단위의 운동 시간이 유의하게 증가되었다.



환자의 가디언 사용후기

- 지속혈당측정기기(CGM)를 처음 사용하면서 얻은 지속적 혈당 정보에 굉장히 놀랐다. 예전엔 불가능했던 음식, 운동 그리고 잠자는 등의 행동이 아침 저녁으로 내 혈당수치에 어떤 영향을 주는지 바로 알 수 있었기 때문이다. 지속혈당측정기기는 중요한 혈당정보를 나에게 제공함으로써 내가 당뇨를 제대로 관리할 수 있도록 해준다. 때때로 내 스스로 감지하기 어려운 위험한 최저 혈당수치를 피할 수 있도록 경보음으로 알려준다.
- 이 기기를 사용하면서 나는 편한 마음으로 저혈당의 두려움 없이 자신감 있게 혈당을 관리한다.

미래에는

- 미래형(통합형)

인슐린펌프 + CGMS + SMBG = ?

인슐린 펜 + CGMS = ?

인공췌장기 ?

제언

- 정확도와 생리적 지연에 대한 기술향상
- 연구
 - Hospital 내에서의 CGM 연구
 - 가장 target 되는 환자 군 선정연구
 - Health Outcome에 대한 장기간(3~5년) 연구
 - 보험 적용의 강력한 Evidence가 되는 연구

핵심 메시지

- 지속혈당감시기기는 혈당의 즉각적인 수치보다 수일간의 혈당패턴을 알려준다.
- 지속혈당감시는 특히 제 1형 당뇨병환자에게 저혈당의 증가 없이 효과적으로 HbA1c를 감소시킨다
- 지속혈당감시는 당뇨병임신부와 제2형 당뇨병환자의 혈당조절에 효과적이다.
- 지속혈당감시와 인슐린 펜의 통합된 모델이나 미래의 인공췌장기에 대한 기초단계로 활용될 수 있다.

감사합니다
사랑합니다



광주, 우리밀빵 195

