DELIBERY ROOM :
Continuous Glucose Monitoring System (CGMS)

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Of pregnancies complicated by diabetes mellitus :

88% : Gestational diabetes
8% : pre-existing DM Type 2
4% : pre-existing DM Type 1
7% (200,000 cases per year)
of all pregnancies, are complicated by gestational diabetes

the Australian Diabetes in Pregnancy Society Consensus statement recommends
a fasting glucose of 4.0–5.5 mmol/L
a postprandial glucose of < 7.0 mmol/L after 1 h
and < 8.0 mmol/L after 2 hours [1,2].

1-Hoffman L, et al. Gestational diabetes mellitus – Management guidelines. The Australasian Diabetes in Pregnancy Society. *Med J Aust*1998;169: 93–97.
2-McElduff A, et al. : The Australasian Diabetes in Pregnancy Society consensus guidelines for the management of type 1 and type 2 diabetes in relation to pregnancy. *Med J Aust* 2005; 183: 373–377.

	Parretti-2001 mg/dl	Yogev-2004 mg/dl
The fasting blood glucose profiles :	71.9 – 78.3 (28 – 38 wks)	75.0
Peak postprandial :	105.0	110.1+/-16
Mean value		83.7
Time peak		70min+/-13

Insulin therapy :

- the fasting blood glucose level > 105 mg/dl
- 2 h post-prandial values > 120 mg/dl

The euglycaemic is a
--target for fetal well-being
--prevention of episodes of hypoglycemia
(ketoacidosis and anaerobic metabolism)

1- Parretti E. et al. First trimester maternal glucose levels from diurnal profiles in nondiabetic pregnancies Diabetes Care 2001;24:1319
2- Yogev Y et al.: Diurnal glycemic profile in obese and normal weight nondiabetic pregnant women Am J Obstet Gynec 2004;191: 949

When does the **physiological peak** of post-prandial glucose occur ?

--Post-Pra. Glucose Level > Pre-Pra.[1]
(insulin treat adaptation)

--↑ Correlation of 1 hr glucose levels than 2 hrs..... [1,2]

--Relation SMBG / Complication : unsatisfactory [3]
(4-6-8 glucose measurements/day not reflect the 24 h profile)

SMBG : Self Monitorng Blood Glucose

[1] Combs CA et al. Relation-ship of fetal macrosomia to maternal post-prandial glucose control during pregnancy. Diabetes Care 1992;15:1251-1257
[2] Parretti E. et al.: Third-trimester maternal glucose levels from diurnal profiles in non-diabetic pregnancies. Diabtes Care 2001;24:1319-1323
[3] Verma A. et al. Relationship between plasma glucose levels in glucose intolerant women and newborn macrosomia. J Matern Fetal Med 1997; 6: 187-193

Do **non-diabetic and diabetic** pregnant women have **different** post-prandial **glucose profile** ?

82 +/- 18 min Glucose Peak in non–diabetic group
74 +/- 23 min Glucose Peak in diabetic group

not significant

60 min ???
90 min ???
120 min ????

..... but ..... few studies are available about the **pre- / post prandial glucose curves** in patients with GDM and health pregnant women

What is the **optimal time for post-prandial glucose measurement** rated according to clinical outcome ?

Buhling KJ et al: Optimal timing for postprandial glucose measurement in pregnant women with diabetes and a non-diabetic pregnant population evaluated by the continuous glucose monitoring system (CGMS). J Perinat Med 2005;33:125-131

THE GOAL IN TREATING PATIENTS WITH GESTATIONAL DIABETES IS TO ACHIVE GOOD GLYCEMIC CONTROL

Significant Difference between the measurements

at 120 min and 135 min Post-Prandial $P < 0.05$

at 75 min and 105 min , by clinical outcome $P < 0.05$

at 60 min to 135 min, for mode of delivery $P < 0.05$

at 60 min to 135 min, for birth weight percentile $P < 0.05$

....no evidence for the recommended post-prandial cut-off values

60 min ???..... To short

120 min ????.... To long

.**Optimal Time : 45 – 120 min post-prandial**

...**but we would prefer a 60 min**, because patients

can calculate this more easily

can have more freedom to eat

Buhling KJ et al: Optimal timing for postprandial glucose measurement in pregnant women with diabetes and a non-diabetic pregnant population evaluated by the continuous glucose monitoring system (CGMS). J Perinat Med 2005;33:125-131

Hyperglycemia :

--in later stages of pregnancy is associated with an increased risk of
-----macrosomia,
-----birth weight

SMBG = an incomplete picture
= difficult to interpret
= difficult to extrapolate necessary information.
= **the ideal timing to monitor hypo- or hyperglycemia remains a matter of debate**

Acceptable regimen for blood glucose monitoring by SMBG is to measure :
-- before and 1 h after meals,
-- prior to going to sleep,
-- during the night (nocturnal hypoglycemia)
-- 8 values / 24 hrs ?????

SMBG : Self Monitorng Blood Glucose

Hyperglycemia :

•In a period of 24 h,
blood sugar in patients with diabetes **fluctuates dramatically**, and many of these occurrences are undocumented and unnoticed when using SMBG only 6 to 8 times per day.

•The maternal hyperglycemia causes ---a **hyperplasia of pancreatic** βcells resulting **iperinsulnemia fetal** and **hyperplasia of adipocytes**

But, .. The asymptomatic hypoglicemia ? (< 60 mg/dl, especially at night)

Hypoglicemia

Maternal hypoglycaemia is
--a common occurrence in pre-existing diabetes in pregnancy,
--a potentially damaging to mother and fetus,
(in the first trimestercan be teratogenic)

-First Self-sampling[1] for blood sugar determination - 1962

1 Keen H et al. Self-sampling for blood sugar . Lancet 1962; 1: 1037-1040

Continuous Glucose Monitoring System (CGMS)

displays glucose levels

every 1 min / 5 min/ 72 hrs

in non-pregnant and pregnant patients with diabetes

interstitial fluid glucose is similar to plasma glucose

--day-to-day glucose variability
--complete view of a glucose profile
--glycaemic control during the first trimester
--measure the glucose content of interstitial fluid
--**measure glucose levels during delivery**
--allows the detection of otherwise unnoticed hypo- and hyperglycemic episodes

Food and Drug Administration-approved devices :
--CGMS (Medtronic, Inc.,Sylmar, CA)
--Guardian REAL-Time System (Medtronic MiniMed, Northridge, CA)
--SEVEN system (DexCom,San Diego, CA),
--FreeStyle Navigator (Abbott Diabetes Care, Alameda, CA)

Continuous Glucose Monitoring System (CGMS)

continuous glucose profile allows you to:
-reduce the range of glucose excursion in patients insulin treated
-reduce the costs of insulin therapy
-reducing maternal-fetal-neonatal complications
-identify the early episodes of maternal hyperglycemia and hypoglycemia

15 gravid women with type 1 diabetes:
strong accuracy of the CGMS in comparison to SMBG

Kerssen A. et al: The continuous glucose monitoring system during pregnancy of women with type 1 diabetes mellitus: accuracy assessment. Diabetes Technol Ther 2004; 6: 645-651

SMBG : Self Monitorng Blood Glucose

Continuous Glucose Monitoring System (CGMS)

47 Israeli women with GDM compared the glycemic profile by CGMS to SMBG of glucose after a 72-h period.

--23 women were treated with diet alone

--24 with diet and insulin.

CGMS for 72 h, a total of 763 +/- 62 glucose measurements / patient (versus 18–24 SMBG measurements /72-h /patient).

•In the insulin-treated group,CGMS revealed 132 +/- 31 min / day of hyperglycemia (glucose level >140mg=dL) that was undetected by SMBG.

•

•14 insulin-treated women were found to nocturnal hypoglycemia, undetected by SMBG.

•In the diet-treated group experienced 94 +/- 23 min/ day of undetected hyperglycemia.

•Through the information supplemented by CGMS, therapeutic regimens were adjusted for 36 of the 47 patients.

Chen R et al.: Continuous glucose monitoring for the evaluation andimproved control of gestational diabetes mellitus J Materrn Fetal Neonatal Med 2003;14:256-260

Continuous Glucose Monitoring System (CGMS)

55 pregnant women – 37 with gestational diabetes (10 type 2 and 8 type 1)

62% : showed undetected postprandial hyperglycaemia and overnight hypoglycaemia.

CGMS is a well-tolerated clinically useful tool in the management of gestational diabetes and pre-existing diabetes in pregnancy.

Mc Lachlan K et al. : The role of continuous glucose monitoring in clinical decision-making in diabetes in pregnancy. Aust N Z J Obstet Gynaecol 2007; 47: 186-190

Summary of Literature Review

Authors (year)	*Participants*	*Findings*
Feldman et al. (2003)	Type 1, non-pregnant ($n=30$)	97.6% of readings within clinically acceptable zones
Gross et al. (2000)	Non-pregnant patients ($n=135$), 87% type 1	96.2% readings within clinically acceptable zones
Clarke et al. (2005)	Type 1 non-pregnant ($n=16$)	Navigator more accurate than CGMS during hypoglycemia
Kerssen et al. (2004)	Type 1, pregnant ($n=15$)	93.8% of readings within clinically acceptable zones
Chen et al. (2003)	GDM, pregnant ($n=57$)	CGMS detected hyperglycemia and nocturnal hypoglycemia, otherwise undetected by SMBG. These findings were used to adjust therapeutic regimen in patients.
McLachlan et al. (2007)	GDM, pregnant ($n=37$); type 2, pregnant ($n=10$); type 1, pregnant ($n=8$)	62% of CGMS traces detected hyperglycemia and nocturnal hypoglycemia and were used to alter therapeutic regimen. 77% patient satisfaction
Yogev et al. (2003)	Type 1 pregnant ($n=6$); GDM, pregnant ($n=2$)	Therapuetic changes made based on CGMS information showed a reduction in hyperglycemia and nocturnal hypoglycemia.
Garg et al. (2006)	Type 1, non-pregnant ($n=75$); type 2, non-pregnant ($n=16$)	95.4% of reading within clinically acceptable zones Real-time access to CGM readings decreased time spent in hyperglycemia and nocturnal hypoglycemia, while increasing time in target glucose range when compared to patients using SMBG alone.
Murphy et al. (2008)	Type 1, pregnant ($n=46$); type 2, pregnant ($n=25$)	CGM during pregnancy improves maternal HbA1c in the third trimester, decreases infant birth weight, and reduces risk of macrosomia.
Voelme et al. (2007)	Type 1, pregnant ($n=12$)	Real-time CGM during pregnancy improves maternal HbA1c and decreases infant birth weight.
Kestilä et al. (2007)	GDM, pregnant ($n=73$)	CGM detected higher number of GDM women in need of antihyperglycemic medication than SMBG alone.
Yogev et al. (2004)	Pregnant, without diabetes, normal and obese weight ($n=57$)	Characterization of obese and normal weight, without diabetes glycemic profiles using CGM

Continuous Glucose Monitoring System (CGMS)

Yogev (2004) used CGMS
to monitor pregnant women without diabetes
in order to create a normoglycemia profile
for comparison to women with pregnancies complicated by diabetes.

57 obese and **normal weight** women
without diabetes were monitored for 72 h with the CGMS.

Fasting blood glucose was 75 +/- 12mg/dL
mean blood glucose level was 110 +/- 16mg/dL
CGMS, postprandial glucose peaks was 70 +/- 13 min.

The obese women displayed
--higher postprandial glucose peak values,
--increased time interval for attainment of the glucose peak,
--lower mean blood glucose during the night.

Interestingly, no difference was found between
obese and normal weight women
regarding fasting and mean blood glucose.

Yogev Y, et all. : Diurnal glycemic profile in obese and normal weight nondiabetic pregnant women. Am J Obstet Gynecol 2004;191:949-953.

The primary aim :

CGMS in mothers with DM **in labour**, and to review our current guidelines regarding maternal glycaemic control.

A second aim : to investigate the relationship between

The maternal glucose concentrations **2 h before delivery** and

the **postnatal glucose adaptation of the newborn**

Participating women : 20 pregnant women insulin-treated DM

(17 with Type 1 DM, 1 Type 2 DM , 2 gestational DM)

- ≥ 37 wks
- insulin-treated
- planned vaginal delivery,
- CGMS monitoring during the last 2 h prior to delivery
- All were treated with an intensive multiple daily insulin regimen or insulin pump
- CGMS monitoring was initiated in the delivery room
- 5 mothers were excluded
- Accurate readings for at least 2 h prior to delivery in 15 women.

Stenninger E et al. : Continuous Subcutaneous Glucose Monitoring System in diabetic mothers during labour and postnatal glucose adaptation of their infants Diabet. Med. 2008;25: 450–454

Definition of hypoglycaemia

The Swedish Paediatric Association (1997) defines hypoglycaemia as **capillary blood glucose < 2.2 mmol/l** for both preterm and term infants.

9/15 (60%) infants had blood glucose concentrations < 2.2 mmol/l, most often 2 h after birth;

5/15 (33%) infants needed glucose infusions

.....even though we considered the diabetic women to have good glycaemic control

CGMS recordings in the mother

Mean glucose concentration 0–120 min before delivery were significantly associated with the need for glucose infusion in the newborn infant .

The mothers of the infants who received glucose had a **significantly higher mean glucose concentration 2 h before delivery** than those of infants who did not require glucose [7.5 ± 2.2 mmol/l vs. 5.3 ± 1.5 mmol/l; *P* = 0.028].

Stenninger E et al. : Continuous Subcutaneous Glucose Monitoring System in diabetic mothers during labour and postnatal glucose adaptation of their infants Diabet. Med. 2008;25: 450–454

- **Postnatal infant hypoglycaemia is probably induced at the time of labour.**

- **High maternal blood glucose concentrations will increase the risk of hypoglycaemia in the offspring** [1,2]

Glucagon levels play an important role in the enzymatic initiation and maintenance of neonatal glucose production from the liver [3], and postnatal hypoglycaemia in infants of diabetic mothers may also be caused by an insufficient glucagon response [4]

The **CGMS method** : the best in detecting episodes of hyper- and hypoglycaemia and for the assessment of **day-to-day glucose variability** [5,6]

1- Kühl C, et al.: Metabolic events in infants of diabetic mothers during the first 24 hours after birth. Acta Paediatr Scand 1982; 71 : 19–25.
2- Miodovnik M, et al.: Management of the insulindependent diabetic during labour and delivery. Am J Perinatol 1987; 4: 106–114.
3- Girard JR, et al. : Control of rat liver phosphorylase glucose-6-phosphatase and phosphoenolpyruvate carboxykinase activities by insulin and glucagon during the perinatal period. Enzyme 1973; 15: 272–285.
4- Bloom SR, et al. : Failure of glucagon release in infants of diabetic mothers. Br Med J 1972; 4: 453–454.
5- Buhling KJ, et al. : . Introductory experience with the Continuous Glucose Monitoring System (CGMS; Medtronic Minimed) in detecting hyperglycemia by comparing the Self-Monitoring of Blood Glucose (SMBG) in non-pregnant women and in pregnant women with impaired glucose tolerance and gestational diabetes. *Exp Clin Endocrinol Diabetes* 2004; **112** : 556–560.
6- Kerssen A, et al . : Day-to-day glucose variability during pregnancy in women with Type 1 diabetes mellitus: glucose profiles measured with the Continuous Glucose Monitoring System. *BJOG* 2004; **111** : 919–924.

Conclusions

During delivery,

Patients with DG controlled by diet alone
-does not require administration insulin,
-require control of blood glucose at entry / discharge [1,2].

Patients with DG controlled by insulin therapy,
-you should monitor hourly blood glucose levels
-maintain range 80-110 mg / dL (4.4-6.1 mmol / L) [1,2].

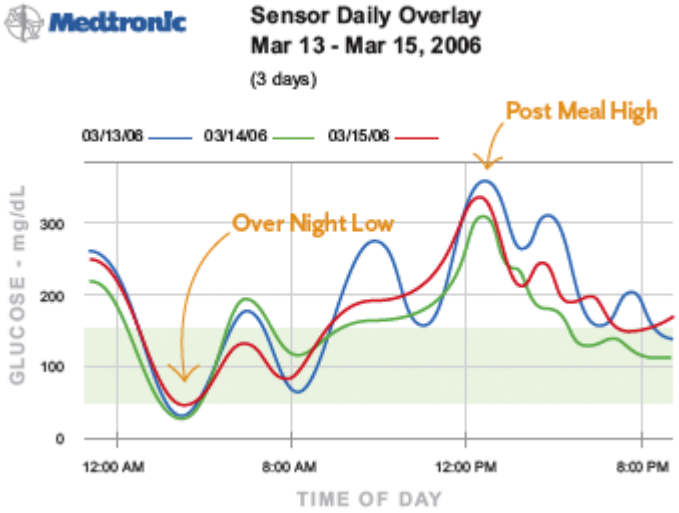
BUT : CGMS PROFILE vs SMBG seems to be a well-tolerated clinical method for close monitoring of maternal glucose concentrations during delivery [3].

1- Turok DK, et al. : Management of gestational diabetes mellitus. Am Fam Physician 2003;Nov 1;68(9):1767-1772
2- Patrelli TS et al. : Management del diabete gestazionale Riv Ost Gin Prat Med Perinat 2007; 22 (2): 5-9
3- Stenninger E et al. : Continuous Subcutaneous Glucose Monitoring System in diabetic mothers during labour and postnatal glucose adaptation of their infants Diabet. Med. 2008;25: 450–454

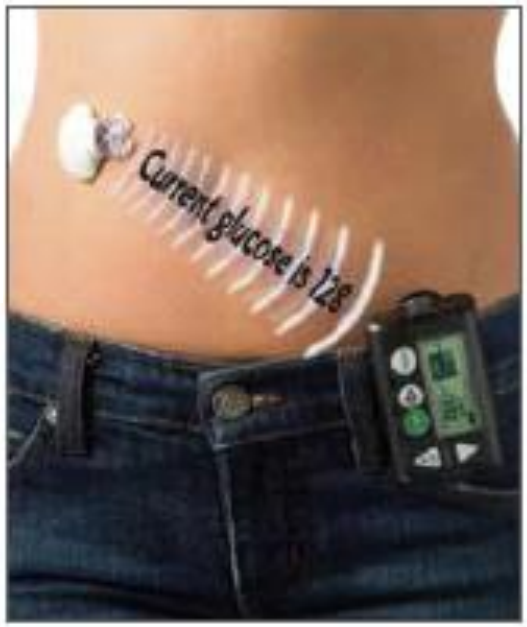
NOTES


10:52
10:52A
24 Hour
128
SHIFT
ESC
ACT


ACT


Medtronic
Sensor Daily Overlay
Mar 13 - Mar 15, 2006
(3 days)
03/13/06
03/14/06
03/15/06
Post Meal High
Over Night Low
GLUCOSE - mg/dL
300
200
100
0
12:00 AM
8:00 AM
12:00 PM
8:00 PM
TIME OF DAY


Transmitter
Glucose
Sensor


Current glucose is 128


CareLink USB


to
108
108

Medtronic

CareLink PERSONAL
SOFTWARE DI GESTIONE DELLA TERAPIA DEL DIABETE

Info personali - Preferenze - Assistenza - Disconnetti

Pagina iniziale | Trasferisci | Diario | Report

Benvenuto/a, Giovanni Nardelli.

Attività recente - Ultimi cinque trasferimenti

Data	Dispositivo	N° di serie

Operazione successiva

- Trasferisci dati dal dispositivo personale
- Inserisci dati nel diario personale
- Genera report

Medtronic

CareLink PERSONAL
SOFTWARE DI GESTIONE DELLA TERAPIA DEL DIABETE

Info personali - Preferenze - Assistenza - Disconnetti

Pagina iniziale | Trasferisci | Diario | Report

Aggiungi dato sui chetoni

Giorno del diario: 10 marzo 2010

Ora: 15 30

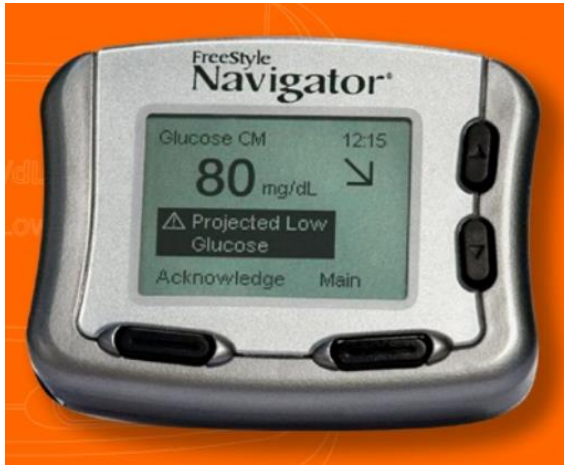
Valore dei chetoni nelle urine: Negativo

Commento:

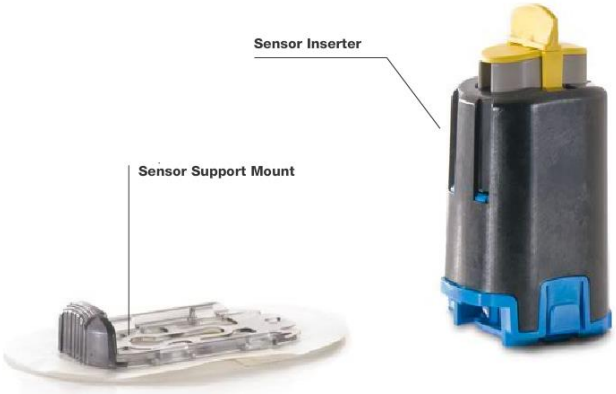
Annulla

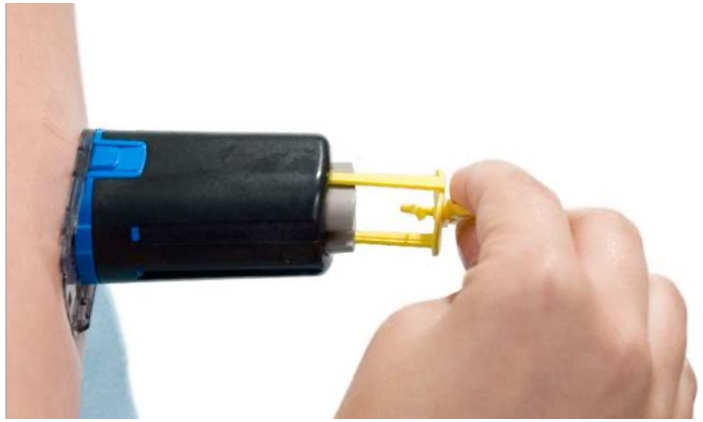
Aggiungi

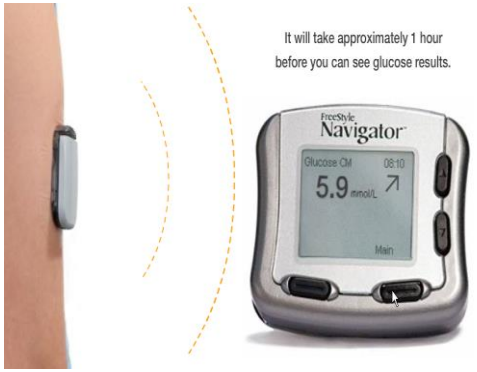
The FreeStyle Navigator system will be available in the second quarter of 2008



Abbott
A Promise for Life


Sensor Inserter
Sensor Support Mount




It will take approximately 1 hour
before you can see glucose results.
FreeStyle
Navigator
Glucose CM
08:10
5.9 mmol/L
Main

Sensor Support Mount
Stays on your skin after Sensor is inserted. Holds the Sensor in place. Attaches the Sensor to the Transmitter.

Sensor
Measures your glucose level.

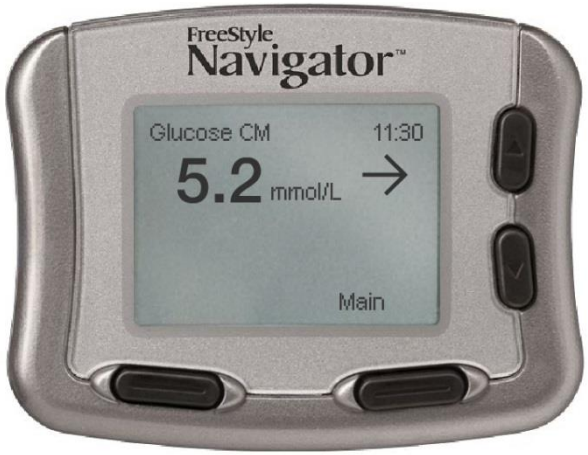
Adhesive Protective Liner
Adhesive that is affixed to your skin.

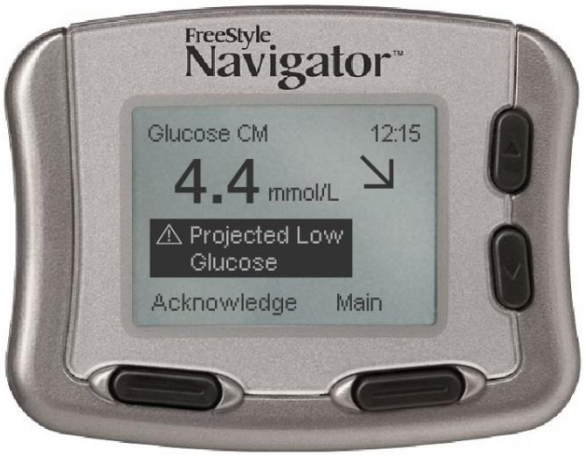
- Attaching the Transmitter
- Removing the Transmitter

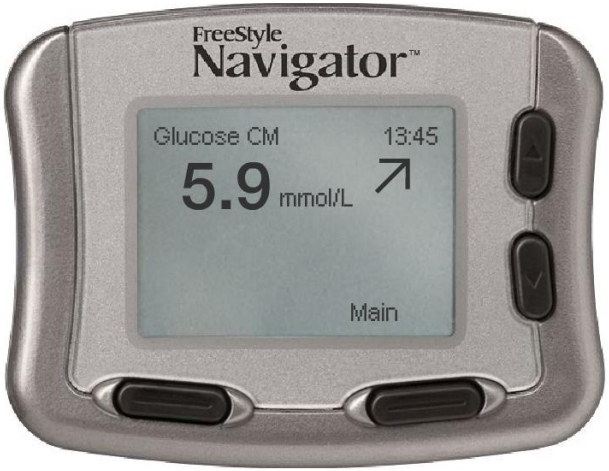
Wireless Transmitter
Connects to the Sensor and sends glucose values to the Receiver once every minute.

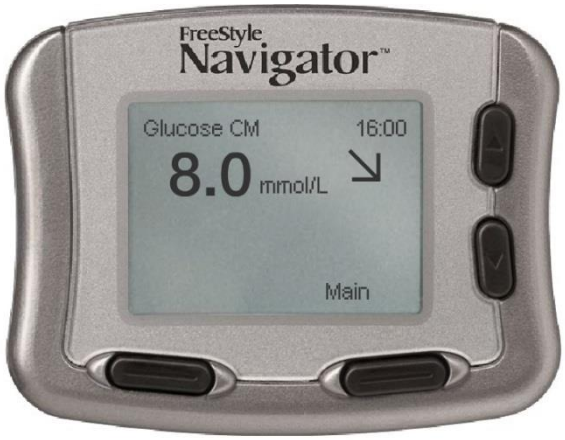
Tabs and Guides
The tabs slide into the Support Mount and hold the Transmitter in place.

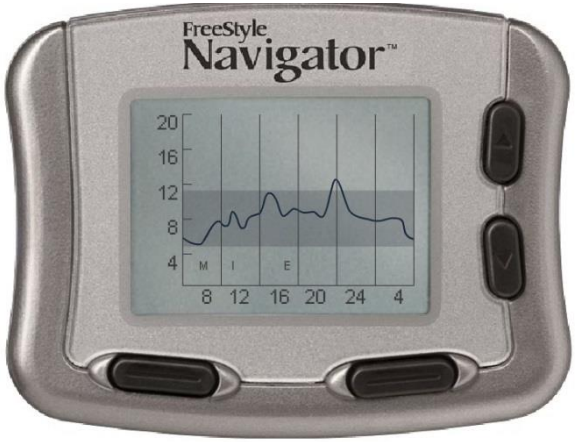
Contact Points
Connect the Sensor to the Transmitter.


FreeStyle
Navigator™
Glucose CM
11:30
5.2 mmol/L
Main


FreeStyle
Navigator™
Glucose CM
12:15
4.4 mmol/L
⚠ Projected Low Glucose
Acknowledge
Main


FreeStyle
Navigator™
Glucose CM
13:45
5.9 mmol/L
Main


FreeStyle
Navigator™
Glucose CM
16:00
8.0 mmol/L
Main


FreeStyle
Navigator™
20
16
12
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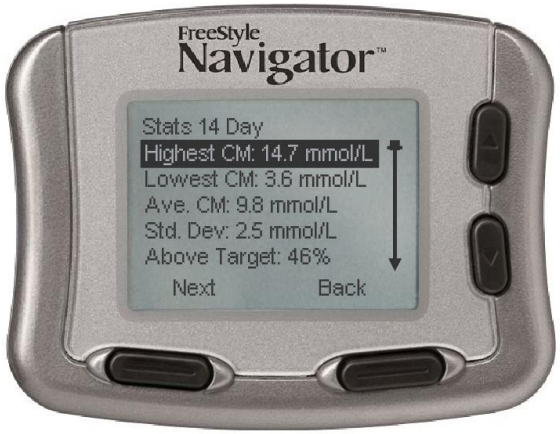
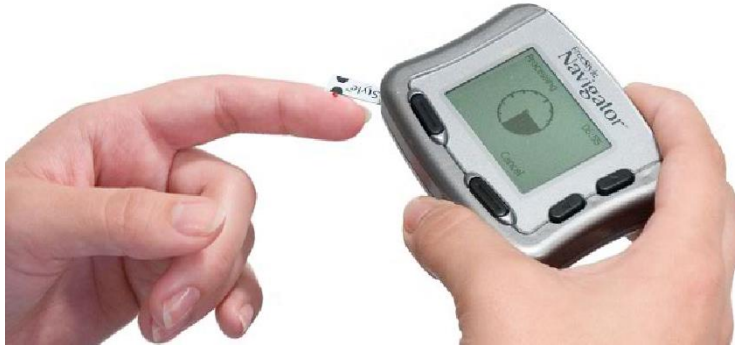
8 12 16 20 24 4

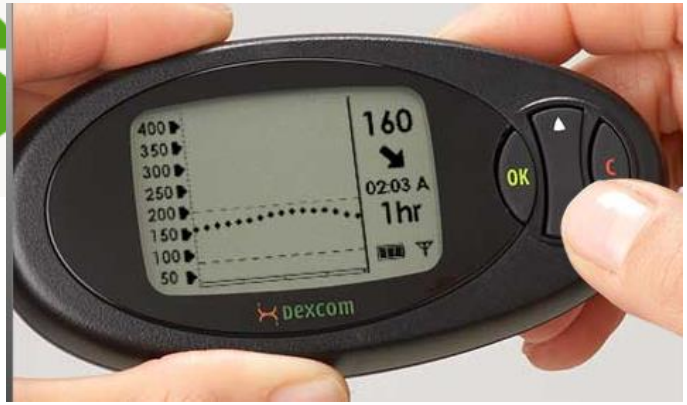

FreeStyle
Navigator™
Stats 14 Day
Highest CM: 14.7 mmol/L
Lowest CM: 3.6 mmol/L
Ave. CM: 9.8 mmol/L
Std. Dev: 2.5 mmol/L
Above Target: 46%
Next
Back

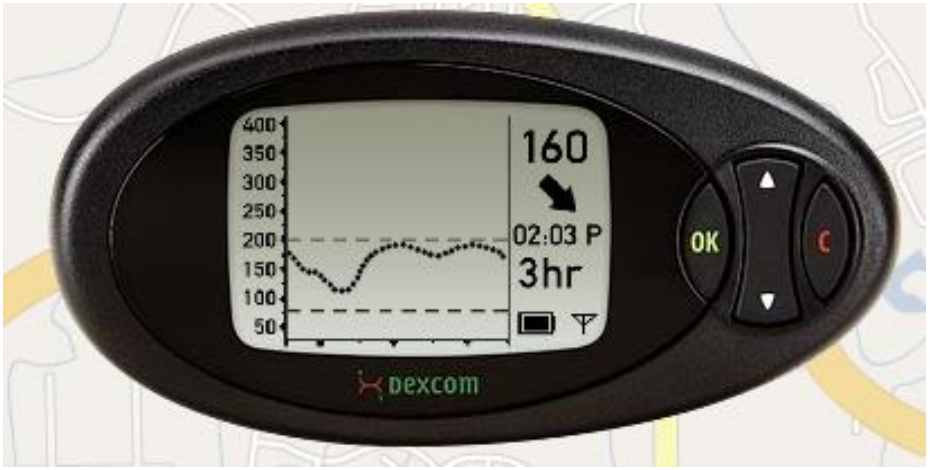

FreeStyle
Navigator

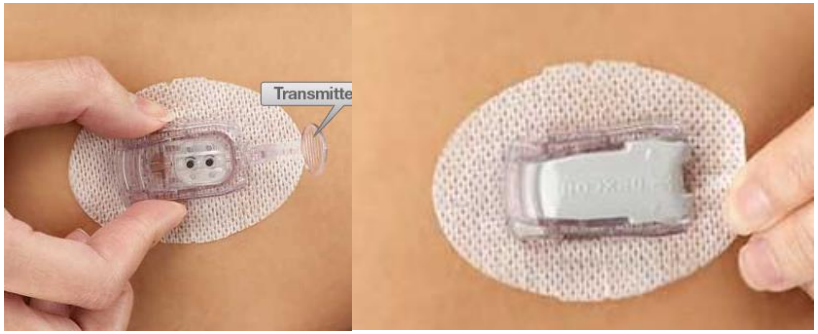

FreeStyle
Navigator
Glucose BG
11:30
6.7
mmol/L
Control Solution?
Yes
No

seven®PLUS

continuous glucose monitoring system







An arrow pointing right means your glucose is constant or steady. It's not increasing or decreasing more than 1 mg/dL each minute.

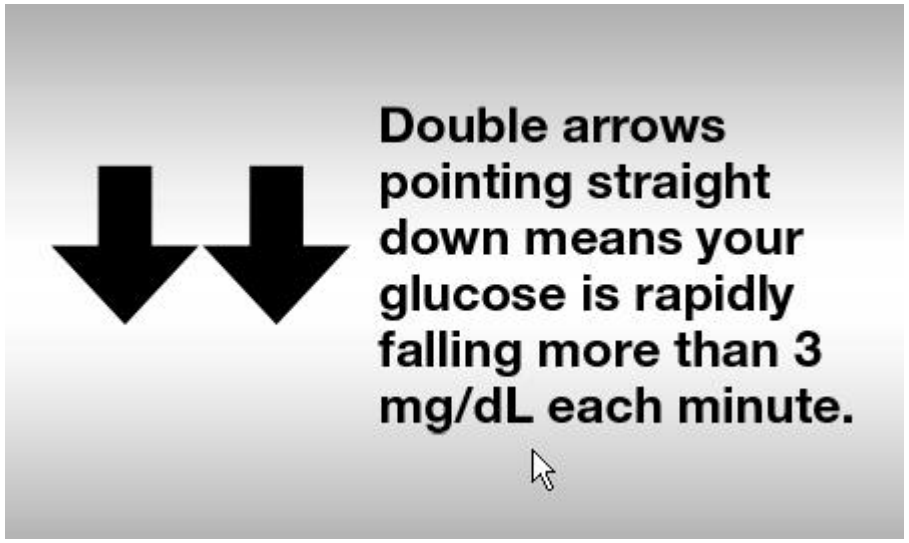
A diagonal arrow pointing upward means your glucose is slowly rising 1 to 2 mg/dL each minute.

A single arrow pointing straight up means your glucose is rising 2 to 3 mg/dL each minute.

Double arrows pointing straight up means your glucose is rapidly rising more than 3 mg/dL each minute.

A diagonal arrow pointing downward means your glucose is slowly falling 1 to 2 mg/dL each minute.

A single arrow pointing straight down means your glucose is falling 2 to 3 mg/dL each minute.



Alerts and ALARM

Low Glucose ALARM = 55 mg/dL

Thanks for your attention