SMBG: quale spazio nell'era delle tecnologie avanzate. Norme ISO e Accuratezza

Roma, 21 giugno 2019

dr.ssa Donatella Bloise

Referente Polo Diabetologia Ariccia, RM

L’automonitoraggio glicemico

A chi serve?

- ✓ DM T1
- ✓ DM T2
- ✓ Diabete Gestazionale

DM T1 e Automonitoraggio Glicemico

Opzione per il controllo glicemico:

- Continuous Glucose Monitoring (esterno/impiantabile)

  circa 60%

  - la calibrazione con glicemia capillare
  - in caso di ipoglicemia glicemia capillare

- Flash Glucose Monitoring (autotaratura)

  - in caso di ipoglicemia glicemia capillare
  - in caso di dubbio glicemia capillare

- SMBG

  - scelta personale (rifiuto, fattore ansiogeno)
  - allergie (colla?) vs il sensore
  - continuo distacco sensore

Studio Diamond DM T1 adulti in MDI CGM vs SMBG

Table 2—Within-trial cost-effectiveness results

	Control (n = 53)		CGM (n = 103)		
	Mean (SD)	Median (range or IQR)	Mean (SD)	Median (range or IQR)	P value[b]
Utility and QALYs					
Utility change from baseline	0.0 (0.08)	0 (−0.27, 0.26)	−0.01 (0.09)	0 (−0.33, 0.32)	0.78
QALYs	0.46 (0.06)	0.47 (0.13, 0.50)	0.46 (0.05)	0.47 (0.24, 0.50)	0.61
Costs, $					
Total direct costs	3,118 (3,120)	2,565 (1,928, 3,277)	5,336 (3,070)	5,092 (4,485, 5,726)	**<0.01**
Direct trial personnel	96 (205)	47 (0, 94)	60 (77)	47 (0, 94)	0.41
Medical care	3,022 (3,088)	2,478 (1,880, 3,122)	2,921 (3,065)	2,509 (1,909, 3,095)	0.86
CGM	0 (0)	0	2,554 (0)	2,554	**<0.01**
Total indirect costs[a]	36 (121)	0 (0, 0)	54 (314)	0 (0, 0)	0.85
Missed work	26 (101)	0 (0, 0)	36 (307)	0 (0, 0)	0.65
Poor performance	10 (40)	0 (0, 0)	18 (70)	0 (0, 0)	0.63
Self-management	4,012 (5,529)	2,829 (0, 5,610)	5,473 (10,300)	2,829 (2,259, 5,658)	0.86
Total costs	7,236 (6,097)	5,287 (4,586, 8,223)	11,200 (11,300)	8,178 (6,864, 10,300)	**<0.01**
Total costs[a]	3,154 (3,122)	2,565 (1,999, 3,513)	5,593 (3,083)	5,105 (4,496, 5,780)	**<0.01**
Clinical outcomes: reduction from baseline					P value[b]
HbA_{1c}	−0.39 (0.70)	−0.30 (−3.20, 0.90)	−0.99 (0.77)	−1.00 (−3.00, 0.70)	**<0.01**
Daily strip tests	0.1 (1.5)	0 (−4, 3)	−0.5 (1.5)	0 (−5, 3)	**0.04**
Insulin dose	1.0 (11)	1 (−23, 25)	−2.3 (22)	0 (−145, 52)	0.31
Daily rate of NSHEs	−0.06 (0.27)	0 (−0.93, 0.47)	−0.12 (0.29)	−0.08 (−1.07, 0.63)	**0.02**[c]
BMI	0.27 (1.07)	0.15 (−2.22, 2.80)	0.59 (1.38)	0.56 (−3.42, 5.28)	0.16
Patients having severe hyperglycemic events, n (%)	1 (2)		0 (0)		0.34
Patients having severe hypoglycemic events, n (%)	2 (4)		2 (2)		0.6
Subgroup analyses: reduction from baseline					P value[c]
In the subgroup with high baseline HbA_{1c} (≥8.5%)					
HbA_{1c}	−0.53 (0.60)	−0.50 (−1.5, 0.8)	−1.29 (0.77)	−1.30 (−3, 0.3)	**0.02**
Daily rate of NSHEs	−0.10 (0.29)	−0.07 (−0.93, 0.47)	−0.08 (0.27)	−0.07 (−1.03, 0.63)	0.27
In the subgroup with low baseline HbA_{1c} (<8.5%)					
HbA_{1c}	−0.22 (0.78)	−0.10 (−3.20, 0.90)	−0.63 (0.59)	−0.60 (−1.80, 0.70)	**0.01**
Daily rate of NSHEs	−0.02 (0.25)	0.01 (−0.86, 0.32)	−0.17 (0.32)	−0.14 (−1.07, 0.44)	**0.03**

All costs data were summarized by IQR and other continuous outcomes were summarized by range. IQR, interquartile range. Bold P values indicate statistical significance ($P < 0.05$). [a]Both total indirect costs and total costs did not include the costs from diabetes self-management due to its 20% missing data and huge variability; that is, ~20% patients reported unknown daily number of hours of self-management and seven patients from both groups reported ≥12 h/day and two of CGM users reported 24 h/day. [b]P value was from the Wilcoxon rank-sum test to compare the two groups. [c]P value was from an ANCOVA model adjusting for its baseline outcome and site as a random effect.

W Wan et al Cost-effectiveness of Continuous Glucose Monitoring for Adults With Type 1 Diabetes Compared With Self-Monitoring of Blood Glucose: the DIAMOND Randomized Trial. Diabetes Care 2018 41(6):1227-1234.

DM T2 e Automonitoraggio Glicemico

Non insulino-trattati:

- costi/beneficio per il n. dei controlli necessari
- tipo di farmaco ipoglicemizzante
- delibere regionali
- minore variabilità glicemica

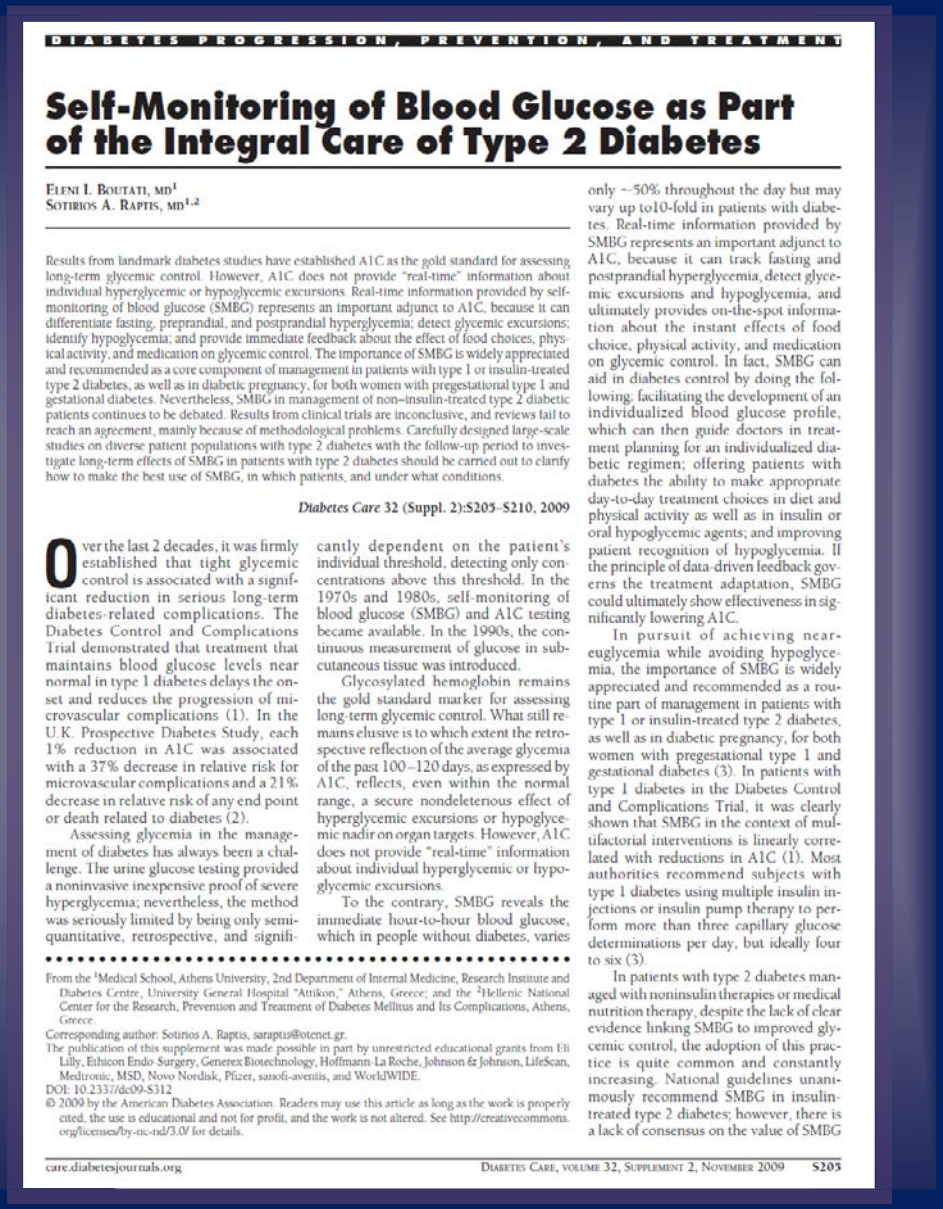
Insulino-trattati (33% AMD 2018; 36% ARNO 2017):

-minore variabilità glicemica

OPZIONI per CGM O FGM:

- delibere regionali
- calibrazione, ipoglicemia, dubbio

L'automonitoraggio della glicemia come parte del programma integrale di cura del DM T2



DIABETES PROGRESSION, PREVENTION, AND TREATMENT

Self-Monitoring of Blood Glucose as Part of the Integral Care of Type 2 Diabetes

ELENI I. BOUTATI, MD[1]
SOTIRIOS A. RAPTIS, MD[1,2]

Results from landmark diabetes studies have established A1C as the gold standard for assessing long-term glycemic control. However, A1C does not provide "real-time" information about individual hyperglycemic or hypoglycemic excursions. Real-time information provided by self-monitoring of blood glucose (SMBG) represents an important adjunct to A1C, because it can differentiate fasting, preprandial, and postprandial hyperglycemia; detect glycemic excursions; identify hypoglycemia; and provide immediate feedback about the effect of food choices, physical activity, and medication on glycemic control. The importance of SMBG is widely appreciated and recommended as a core component of management in patients with type 1 or insulin-treated type 2 diabetes, as well as in diabetic pregnancy, for both women with pregestational type 1 and gestational diabetes. Nevertheless, SMBG in management of non–insulin-treated type 2 diabetic patients continues to be debated. Results from clinical trials are inconclusive, and reviews fail to reach an agreement, mainly because of methodological problems. Carefully designed large-scale studies on diverse patient populations with type 2 diabetes with the follow-up period to investigate long-term effects of SMBG in patients with type 2 diabetes should be carried out to clarify how to make the best use of SMBG, in which patients, and under what conditions.

Diabetes Care 32 (Suppl. 2):S205–S210, 2009

Over the last 2 decades, it was firmly established that tight glycemic control is associated with a significant reduction in serious long-term diabetes-related complications. The Diabetes Control and Complications Trial demonstrated that treatment that maintains blood glucose levels near normal in type 1 diabetes delays the onset and reduces the progression of microvascular complications (1). In the U.K. Prospective Diabetes Study, each 1% reduction in A1C was associated with a 37% decrease in relative risk for microvascular complications and a 21% decrease in relative risk of any end point or death related to diabetes (2).

Assessing glycemia in the management of diabetes has always been a challenge. The urine glucose testing provided a noninvasive inexpensive proof of severe hyperglycemia; nevertheless, the method was seriously limited by being only semiquantitative, retrospective, and significantly dependent on the patient's individual threshold, detecting only concentrations above this threshold. In the 1970s and 1980s, self-monitoring of blood glucose (SMBG) and A1C testing became available. In the 1990s, the continuous measurement of glucose in subcutaneous tissue was introduced.

Glycosylated hemoglobin remains the gold standard marker for assessing long-term glycemic control. What still remains elusive is to which extent the retrospective reflection of the average glycemia of the past 100–120 days, as expressed by A1C, reflects, even within the normal range, a secure nondeleterious effect of hyperglycemic excursions or hypoglycemic nadir on organ targets. However, A1C does not provide "real-time" information about individual hyperglycemic or hypoglycemic excursions.

To the contrary, SMBG reveals the immediate hour-to-hour blood glucose, which in people without diabetes, varies only ~50% throughout the day but may vary up to10-fold in patients with diabetes. Real-time information provided by SMBG represents an important adjunct to A1C, because it can track fasting and postprandial hyperglycemia, detect glycemic excursions and hypoglycemia, and ultimately provides on-the-spot information about the instant effects of food choice, physical activity, and medication on glycemic control. In fact, SMBG can aid in diabetes control by doing the following: facilitating the development of an individualized blood glucose profile, which can then guide doctors in treatment planning for an individualized diabetic regimen; offering patients with diabetes the ability to make appropriate day-to-day treatment choices in diet and physical activity as well as in insulin or oral hypoglycemic agents; and improving patient recognition of hypoglycemia. If the principle of data-driven feedback governs the treatment adaptation, SMBG could ultimately show effectiveness in significantly lowering A1C.

In pursuit of achieving near-euglycemia while avoiding hypoglycemia, the importance of SMBG is widely appreciated and recommended as a routine part of management in patients with type 1 or insulin-treated type 2 diabetes, as well as in diabetic pregnancy, for both women with pregestational type 1 and gestational diabetes (3). In patients with type 1 diabetes in the Diabetes Control and Complications Trial, it was clearly shown that SMBG in the context of multifactorial interventions is linearly correlated with reductions in A1C (1). Most authorities recommend subjects with type 1 diabetes using multiple insulin injections or insulin pump therapy to perform more than three capillary glucose determinations per day, but ideally four to six (3).

In patients with type 2 diabetes managed with noninsulin therapies or medical nutrition therapy, despite the lack of clear evidence linking SMBG to improved glycemic control, the adoption of this practice is quite common and constantly increasing. National guidelines unanimously recommend SMBG in insulin-treated type 2 diabetes; however, there is a lack of consensus on the value of SMBG

From the [1]Medical School, Athens University, 2nd Department of Internal Medicine, Research Institute and Diabetes Centre, University General Hospital "Attikon," Athens, Greece; and the [2]Hellenic National Center for the Research, Prevention and Treatment of Diabetes Mellitus and Its Complications, Athens, Greece.
Corresponding author: Sotirios A. Raptis, saraptis@otenet.gr.
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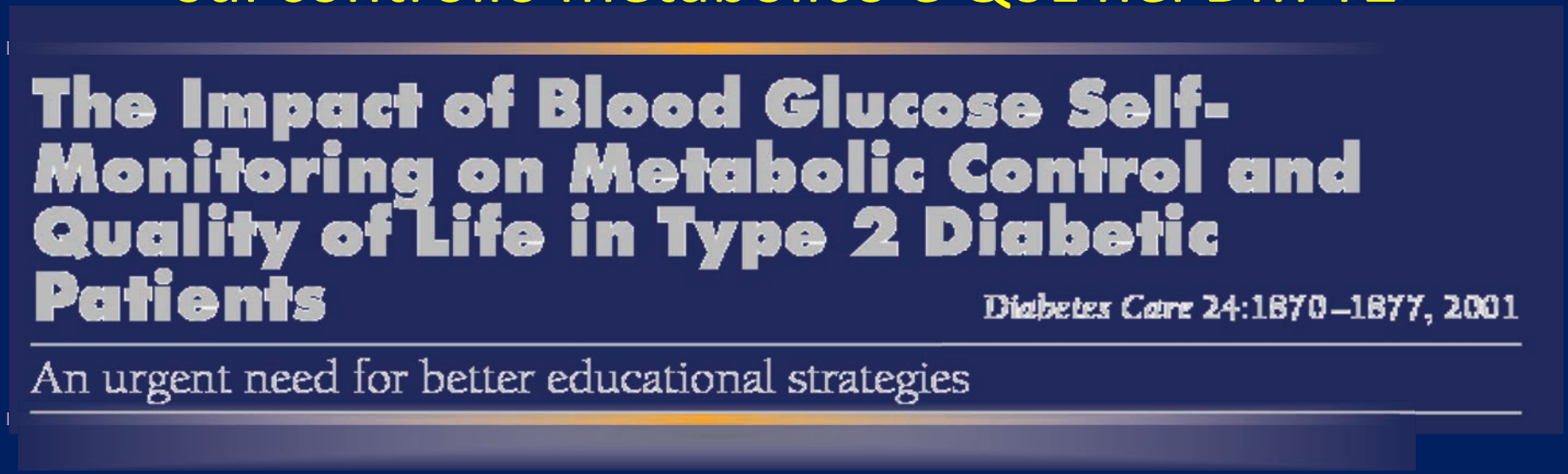
DOI: 10.2337/dc09-S312

L'automonitoraggio glicemico è uno strumento logico per la gestione di una larga parte dei pazienti con DM T2, deve essere proposto con programmi di counseling educazionale strutturati, adattati al profilo psicologico e alla condizione sociale del paziente

Boutati E et al, Diabetes Care 2009

L’impatto dell’automonitoraggio glicemico sul controllo metabolico e QoL nel DM T2



I nostri risultati suggeriscono che l’automonitoraggio della glicemia può avere un ruolo importante nel migliorare il controllo metabolico se è parte di una strategia educativa più ampia, finalizzata alla promozione dell’autonomia del paziente

Franciosi M et al, Diabetes Care 2001; 24: 1870-77

Diabete Gestazionale e Automonitoraggio Glicemico

Regime dieta controlli con SMBG:

- delibere regionali

Insulino-trattate:

OPZIONI per CGM O FGM

- delibere regionali
- calibrazione, ipoglicemia, dubbio

L’automonitoraggio della glicemia quali le indicazioni nel DM?

1. controlli regolari (secondo schema) e continui
2. Pre e post pasto
3. Pre e post situazioni ripetitive (A.F. e …)
4. Situazioni eccezionali, sporadiche
5. In caso di m. intercorrenti/stress emotivo

da non dimenticare l’uso Rassicurativo che ne fa la persona

per sapere “come va”/”come sto”

Obiettivi Clinici del monitoraggio glicemico

- ✓ Stabilire, modificare i goal terapeutici
- ✓ Fornire raccomandazioni per la terapia
- ✓ Valutare l'efficacia della terapia in atto
- ✓ Istruire a interpretare e utilizzare i dati
- ✓ Identificare le ipoglicemie inavvertite

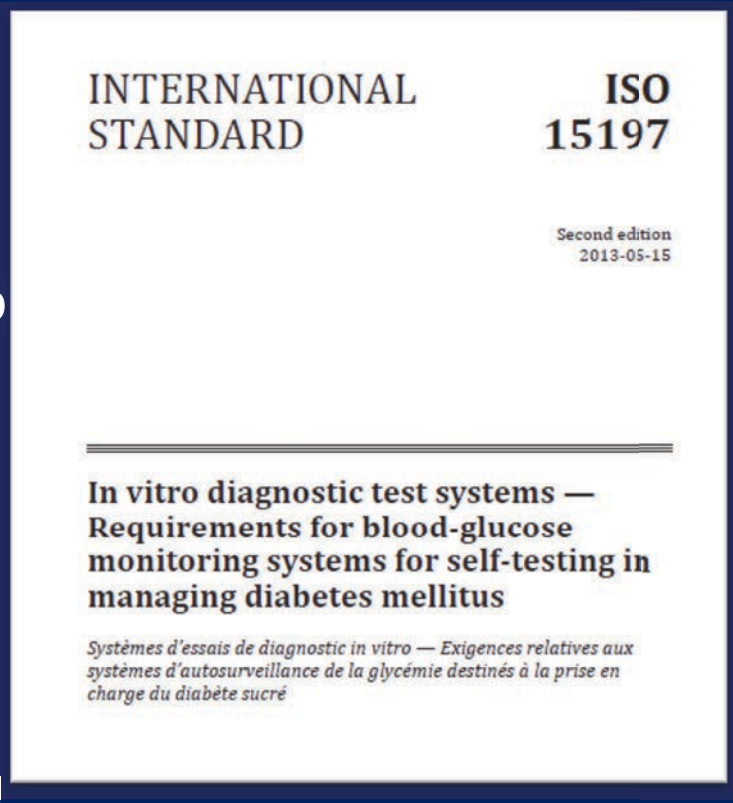
L’automonitoraggio glicemico quali limiti/interferenze

1. Accuratezza del sistema:
   - inerente al glucometro
   - inerente alle strisce reattive (GO, GD) EN ISO 15197:2015
2. Ambientali (T°C, umidità, altitudine)
3. Fisiologiche (volemia, ematocrito, pO2, trigliceridi, bilirubina, uricemia)
4. Farmacologica (vit. C, paracetamolo, dopamina, mannitolo, icodestrina)

M Erbach, et Al,
Interferences and Limitations in Blood Glucose Self-Testing: An Overview of the Current Knowledge
Journal of Diabetes Science and Technology 2016, Vol. 10(5) 1161 –1168

La Normativa ISO 15197

- Per la commercializzazione nella Comunità Europea, tutti i Dispositivi Medici devono possedere il **marchio CE** che ne attesta qualità e funzionalità. Il marchio CE attesta che il prodotto è conforme ai requisiti essenziali richiesti dalla **direttiva europea vigente** per i dispositivi diagnostici in-vitro: **98/79/EC, Annex IV excluding 4,6**
- Questi requisiti possono essere soddisfatti applicando normative armonizzate sviluppate da organizzazioni per la standardizzazione quali la **ISO** (International Organization for Standardization).
- <u>Per i sistemi di automonitoraggio della glicemia si applica la **normativa ISO 15197**.</u>


INTERNATIONAL STANDARD

ISO 15197

Second edition
2013-05-15

In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

Systèmes d'essais de diagnostic in vitro — Exigences relatives aux systèmes d'autosurveillance de la glycémie destinés à la prise en charge du diabète sucré

ISO

CE 0123

Maggio 2003
ISO 15197:2003

Pubblicazione e armonizzazione EN ISO 15197:2003

Maggio 2013:
ISO 15197:2013

Pubblicazione EN ISO 15197:2013 (mai armonizzata)

Giugno 2015:
ISO 15197:2015

Pubblicazione EN ISO 15197:2015 (cambiato solo Annex Z)

13 Maggio 2016: Armonizzazione EN ISO 15197:2015

EN ISO 15197:2015 diventa norma cogente per la presunzione di conformità alla Direttiva 98/79/EC, Annex IV excluding 4,6

Il corpo dei testi delle norme **EN ISO 15197: 2013** e **EN ISO 15197: 2015** sono identici, sono state modificate la Premessa e *l'allegato Z* (dove sono riportati i collegamenti con la direttiva).

Per questo motivo **tutte le validazioni tecniche fatte in funzione della EN ISO 15197: 2013 rimangono valide anche per la nuova versione della norma**.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 98/79/EC *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA Regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 98/79/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

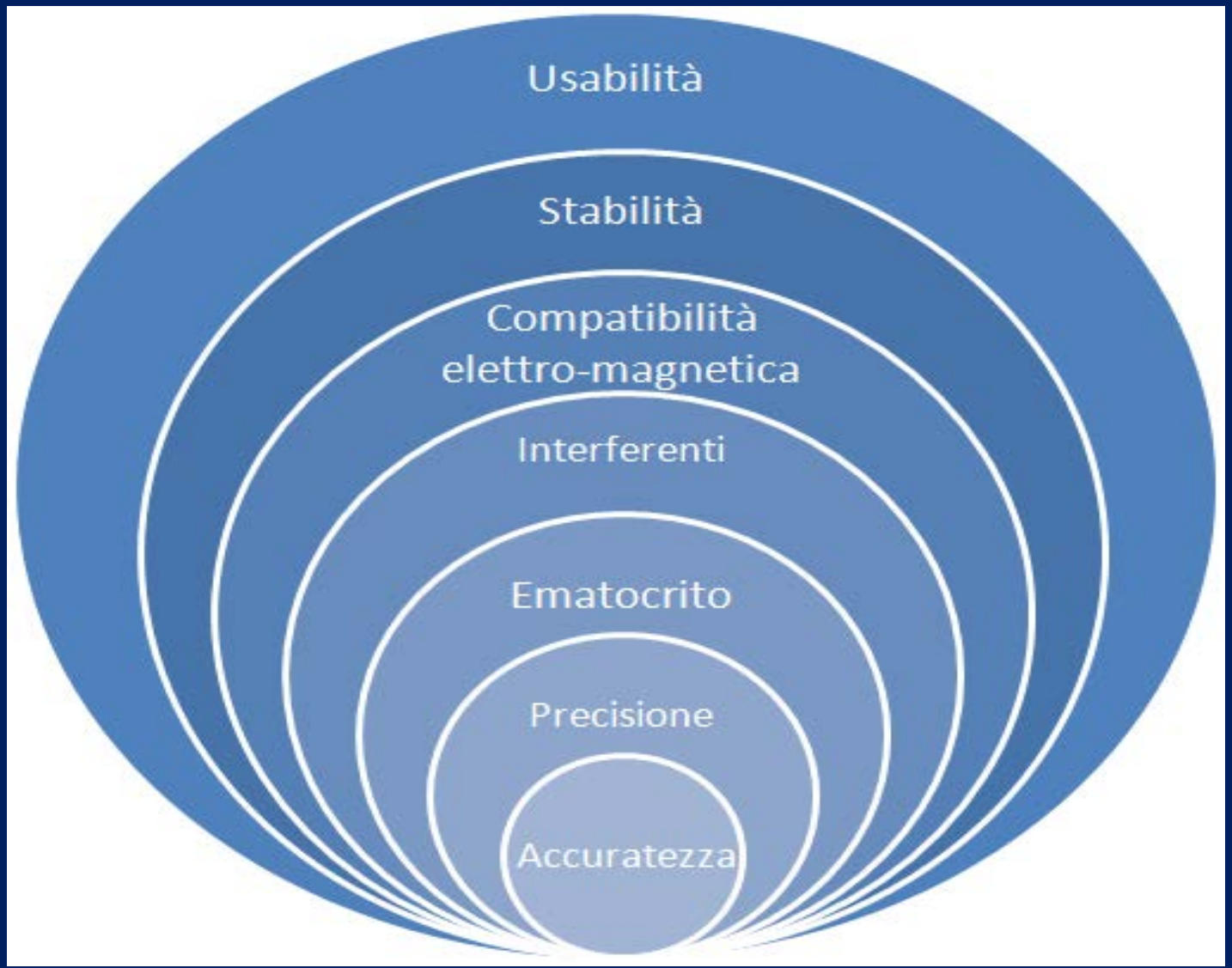
NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 98/79/EC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/notes
4.3	A.2	Referenced clause covers only the first bullet point of the ER. Risk management of blood glucose monitoring instrument is not covered by the referenced clause. Directive 98/79/EC requires manufacturers to eliminate or reduce risks as far as possible. For managing risks associated with in vitro diagnostic medical devices EN ISO 14971:2012 should be applied.
5.11, 5.12	B.3.3	Referenced clauses cover only the temperature (5.11) and humidity (5.12) aspects of the ER (in second bullet)
4.4	B.3.6	
6, 7.2	B.4.1	This ER is covered when accuracy limits are stated by the manufacturer in the IFU.
4.5	B.7.2	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

ISO 15197:2003
vs
ISO 15197:2013



La nuova normativa ISO 15197:2013

- Design and development

  (traceability, risk management, ergonomics/human factors..)

- Safety and reliability

  (EMC, resistance to temperature, humidity, vibrations..)

- Analytical performance (par. 6)
  - Measurement precision
  - System accuracy
  - Influence quantities (hematocrit, interfering substances)
- Information supplied by the manufacturer
- User performance evaluation

Rimasti sostanzialmente invariati rispetto alla precedente ISO 15197:2003

Aggiornati introducendo criteri più specifici e rigorosi

ACCURATEZZA PROTOCOLLO DI VALUTAZIONE

ISO 15197:2003

100 soggetti

min 200 misure

min 2 meter (100 misure x meter)

ISO 15197:2013

100 soggetti

3 lotti di sensori

min 2 meter

min 200 test x lotto (100 x meter)

Tot 600 misure

Distribuzione Livelli di [Glu]

Bin #	Percentage of samples %	Glucose concentration mmol/l (mg/dl)
1	5	≤ 2,77 (≤ 50)
2	15	> 2,77 – 4,44 (> 50 – 80)
3	20	> 4,44 – 6,66 (> 80 – 120)
4	30	> 6,66 – 11,10 (> 120 – 200)
5	15	> 11,10 – 16,65 (> 200 – 300)
6	10	> 16,65 – 22,20 (> 300 – 400)
7	5	> 22,20 (> 400)

ACCURATEZZA CRITERI DI ACCETTABILITA'

ISO 15197:2003

Il **95%** dei risultati deve avere una deviazione dal valore di riferimento:

-entro ± **15 mg/dL** per valori di c di glucosio **<75 mg/dl**,

-entro ± **20%** per valori **≥75 mg/dl**

ISO 15197:2013

(a)

Per ognuno dei 3 lotti:

Il **95%** dei risultati deve avere una deviazione dal valore di riferimento:

- entro ± **15 mg/dL** per valori di c di glucosio **< 100 mg/dl**,

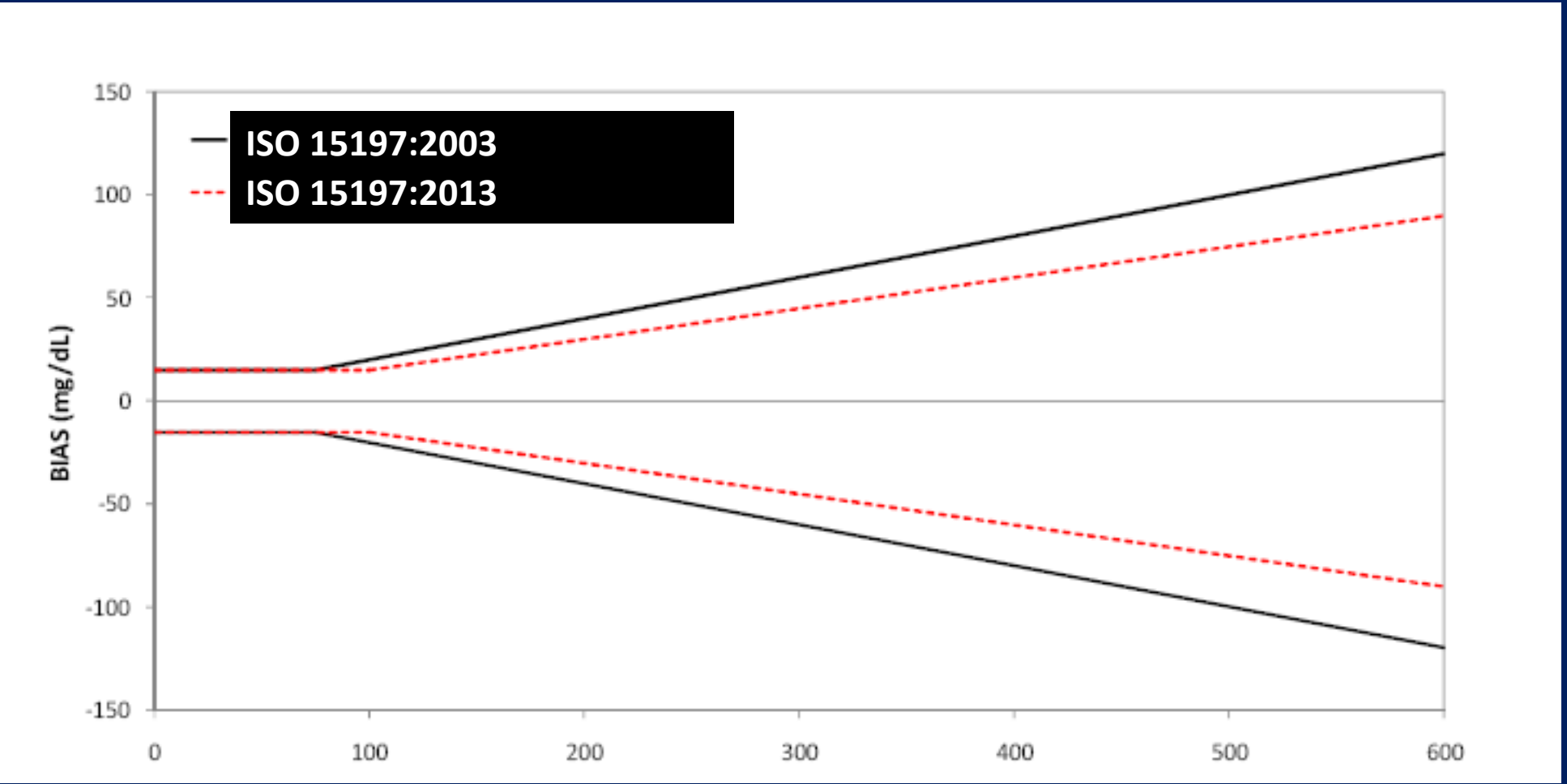
-entro ± **15%** per valori **≥100 mg/dl**

(b)

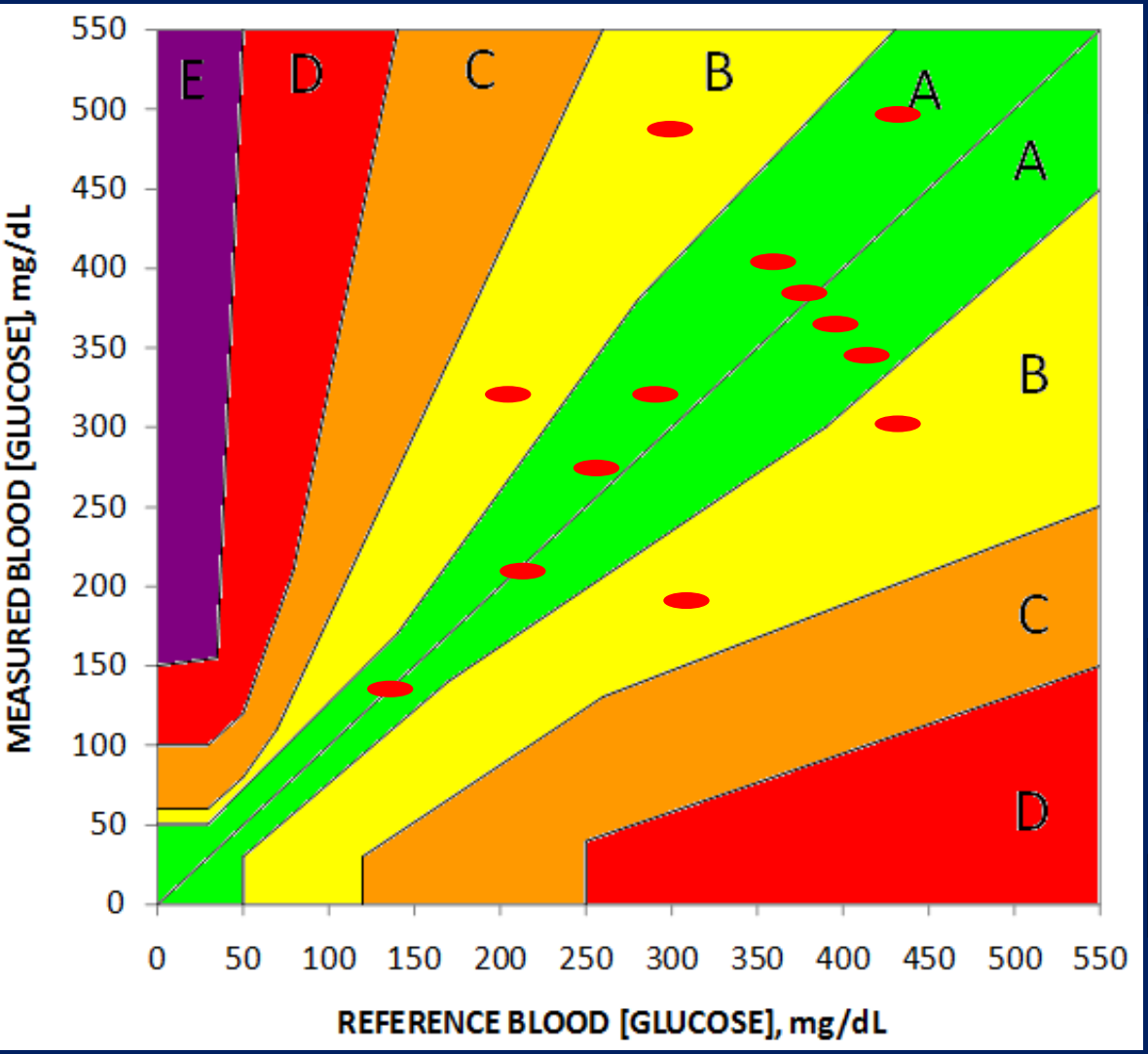
Il **99%** o piu' dei risultati deve cadere nelle zone **A e B** della Parkes Error Grid (o Consensus Error Grid - CEG)

Stability test (30°C) – Closed Pot

Requisito (a) - Nuovi limiti di Deviazione (Bias Plot)



Requisito (b) - Consensus Error Grid (CEG)



A *"Nessun effetto sull'azione clinica"*

B *"Azione clinica alterata – effetto minimo o nullo sul risultato clinico"*

C *"Azione clinica alterata – influenza significativa sul risultato clinico"*

D *"Azione clinica alterata – può portare a un rischio medico significativo"*

E *"Azione clinica alterata – può avere conseguenze pericolose"*

Almeno il 99% dei risultati devono cadere nelle zone A e B della consensus error grid

Parkes JL, Slatin SL, Pardo S, Ginsberg BH. *A New Consensus Error Grid to Evaluate the Clinical Significance of Inaccuracies in the Measurement of Blood Glucose.* Diabetes Care. 2000; 23:1143-1148.

EMATOCRITO PROTOCOLLO DI VALUTAZIONE

ISO 15197:2003

(nessuna indicazione)

NEW!

ISO 15197:2013

5 livelli di Ematocrito (livello centrale = 42% ± 2%, due inferiori e due superiori, includendo le estremità dichiarate in specifica)

3 concentrazioni di Glucosio (ognuna da testare ai 5 livelli di Hct%)

Interval	Glucose concentration mmol/l (mg/dl)
1	1,7 to 2,8 (30 to 50)
2	5,3 to 8,0 (96 to 144)
3	15,5 to 23,3 (280 to 420)

3 lotti di strisce

Min 10 misure per combinazione livello Hct/[Glu]

EMATOCRITO CRITERI DI ACCETTABILITA’

ISO 15197:2003

(nessuna indicazione)

ISO 15197:2013

Per tutti i valori del range dichiarato di **ematocrito,** la deviazione rispetto al valore centrale di Hct (42% ± 2%) deve rientrare**:**

- entro ± **10 mg/dL** per valori di concentrazione di glucosio **< 100 mg/dl**,

- entro ± **10%** per valori **≥ 100 mg/dL.**

ACCURATEZZA: monitoraggio glicemico (MG) vs CGM

La differente definizione di accuratezza dei 2 sistemi non permette la comparazione e il confronto:

- MG ISO **15197:2013**

- CGM/FGM MARD (Mean Absolute Relative Difference)

G Freckmann, Measures of Accuracy for Continuous Glucose Monitoring and Blood Glucose Monitoring Devices
Journal of Diabetes Science and Technology 1 –9, 2018

ACCURATEZZA: MARD monitoraggio glicemico (MG)

TABLE 2. MEAN ABSOLUTE RELATIVE DIFFERENCE COMPARISONS OF THE FOUR SELF-MONITORING OF BLOOD GLUCOSE SYSTEMS

Dataset, system	*MARD comparison method*		
	Manufacturer's method[a]	*GOD*	*HK*
Unaltered samples <70 mg/dL (n=600 measurements)[b]			
1	5.1±0.2	6.7±0.2	5.1±0.2
2	4.4±0.1	4.4±0.1	2.7±0.1
3	13.4±0.3	13.4±0.3	15.2±0.2
4	7.3±0.2	7.3±0.2	6.8±0.2
ISO 15197 (n=600 measurements)[b]			
1	4.8±0.2	5.2±0.2	4.8±0.1
2	4.8±0.1	4.8±0.1	2.8±0.1
3	8.9±0.3	8.9±0.3	9.7±0.3
4	6.5±0.2	6.5±0.2	9.0±0.2

G Freckmann et Al
Accuracy Evaluation of Four Blood Glucose Monitoring Systems in Unaltered Blood Samples in the Low Glycemic Range and Blood Samples in the Concentration Range Defined by ISO 15197
DTT 17-8, -10 2015

L’automomitoraggio della glicemia quali i limiti/interferenze

1. Riproducibilità del dato

   -training da parte di personale formato

2. Errori nell’uso (affidabilità)
   - misurazione dopo aver lavato le mano!
   - mantenimento corretto delle strisce, scadenza

M Erbach, et Al,
Interferences and Limitations in Blood Glucose Self-Testing: An Overview of the Current Knowledge
Journal of Diabetes Science and Technology 2016, Vol. 10(5) 1161 –1168

3. Correttezza nell’annotazione dei risultati

4. Completezza del dato (contestualizzazione)

5. Analisi “a scalini” (non profili delle 24 ore)

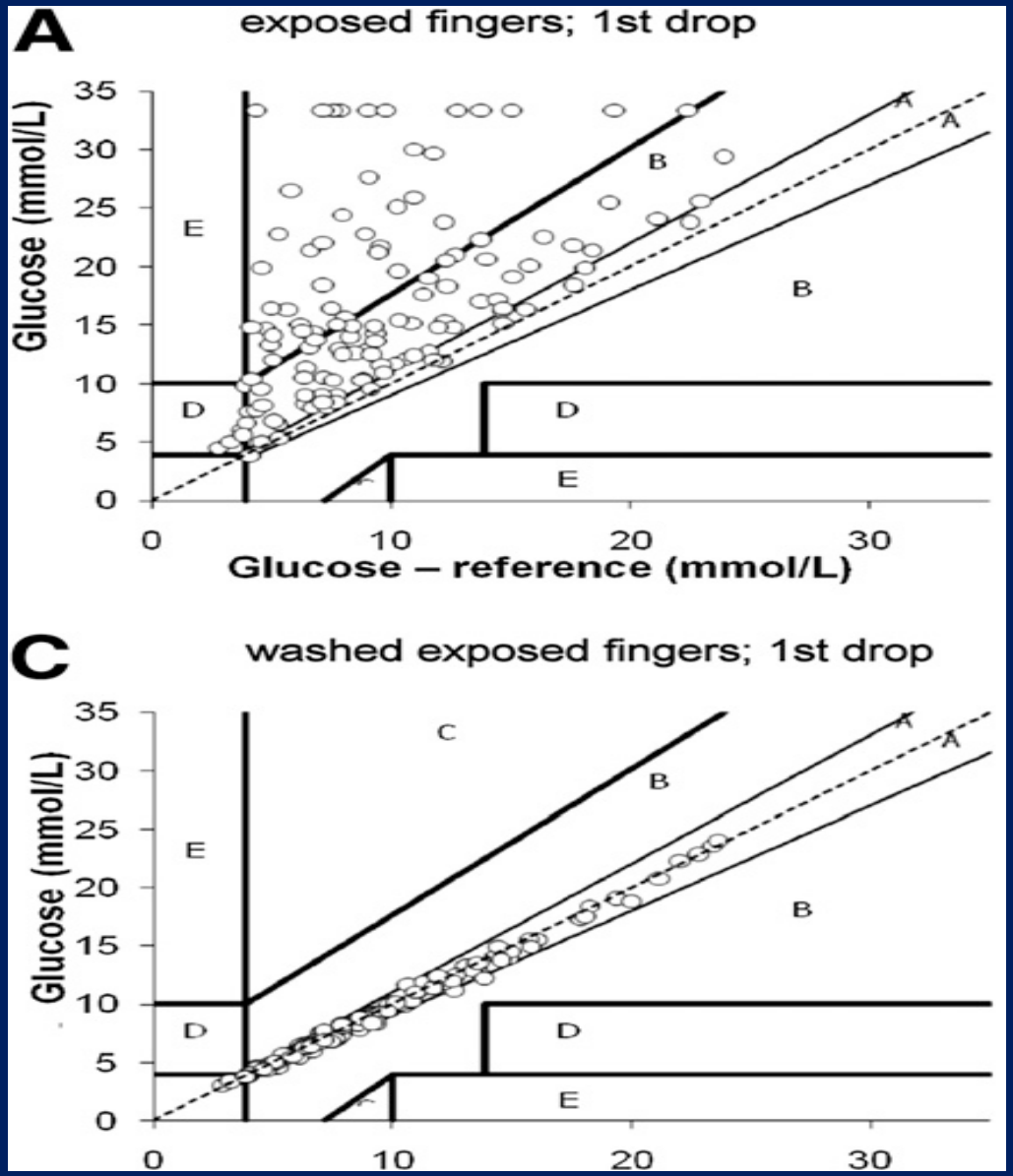
Scarsa attenzione alla tecnica comporta inaffidabilità

La contaminazione cutanea riduce l'affidabilità
della lettura della glicemia (es: 1 ora dopo aver toccato la frutta)

Esposizione	Mano lavate	Mano esposte (non lavate)	Mano strofinate 1 volta con alcol	Mano strofinate 5 volte con alcol
Sbucciare Arancia	97 mg/dl	171 mg/dl	119 mg/dl	119 mg/dl
Grappolo d'uva	94 mg/dl	360 mg/dl	274 mg/dl	130 mg/dl
Sbucciare kiwi	90 mg/dl	184 mg/dl	144 mg/dl	106 mg/dl

J Hortensius, et al. Self-Monitoring of Blood Glucose: The Use of the First or the Second Drop of Blood. Diabetes Care 34:556–560, 2011

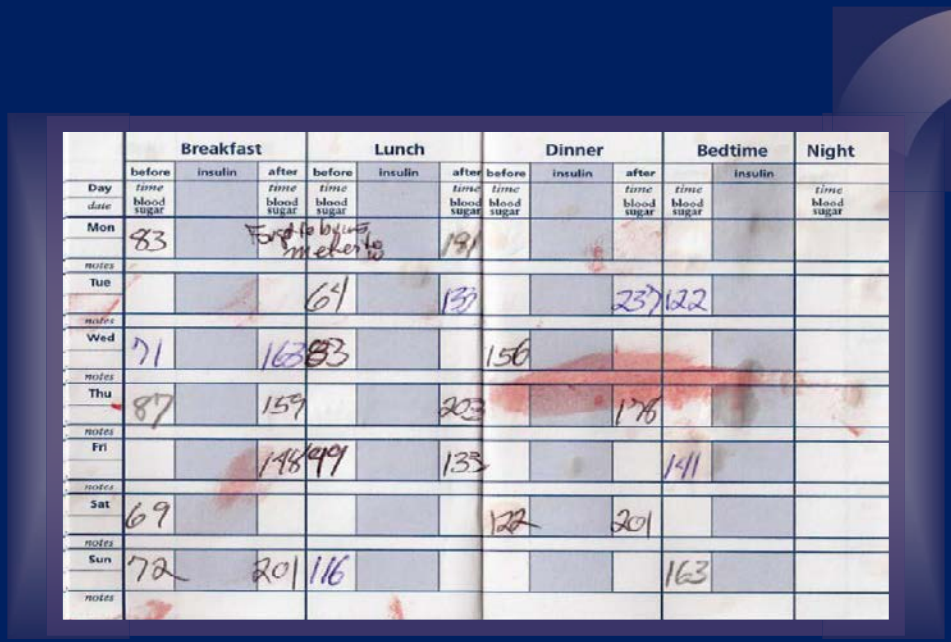
Scarsa attenzione alla tecnica comporta inaccuratezza



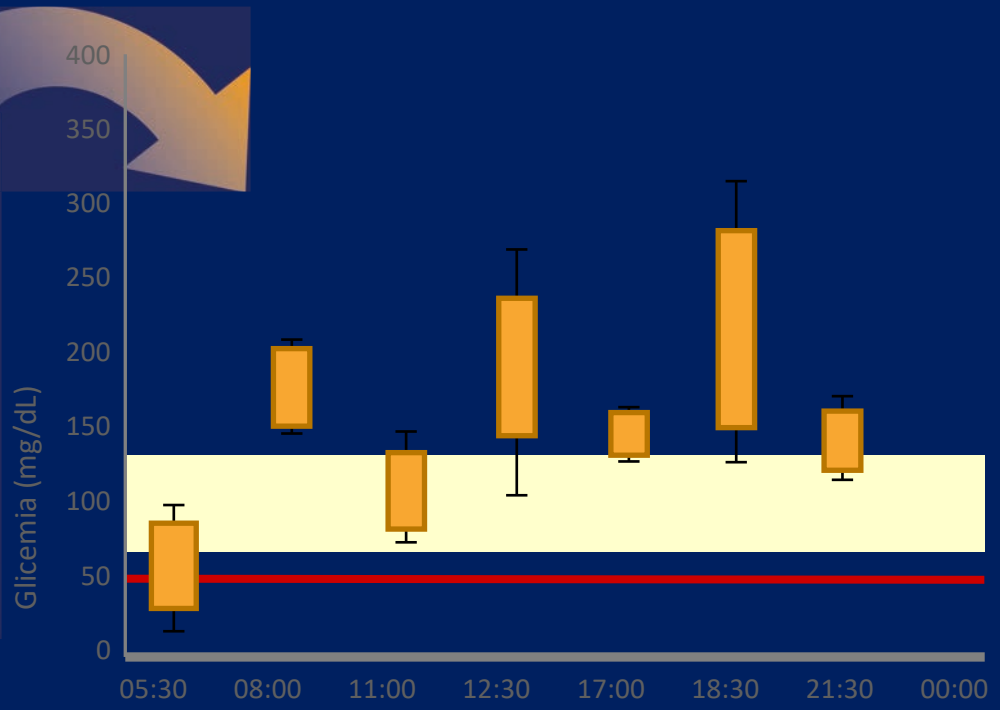
J Hortensius, et al. Self-Monitoring of Blood Glucose: The Use of the First or the Second Drop of Blood. Diabetes Care 34:556–560, 2011

Information Management

Con il termine “Information Management” si intende la gestione dei dati provenienti dall’autocontrollo trasformandoli in informazioni utilizzabili sia dal medico che dal paziente per migliorare la gestione stessa del diabete



	Breakfast			Lunch			Dinner			Bedtime		Night
	before	insulin	after	before	insulin	after	before	insulin	after		insulin	
Day / date	time / blood sugar		time / blood sugar	time / blood sugar		time / blood sugar	time / blood sugar		time / blood sugar	time / blood sugar		time / blood sugar
Mon	83					191						
notes												
Tue				64		137			237	122		
notes												
Wed	71		163	83			156					
notes												
Thu	87		159			203			176			
notes												
Fri			148	99		133				141		
notes												
Sat	69						122		201			
notes												
Sun	72		201	116						163		
notes												



Information Management

Per migliorare l'efficienza clinica

- Semplifica la raccolta dei dati e la loro analisi assicurando accuratezza
- Consente un risparmio di tempo
- Permette al medico di valutare con chiarezza e semplicità una grossa mole di dati
- Offre la possibilità di calcolare nuovi parametri per un compenso glicemico ottimale

Pattern Management

Le medie della glicemia pre e postprandiale, il numero dei test effettuati e le deviazioni standard possono aiutare le persone e i professionisti a valutare i pattern di glicemia[1].

Il **numero di test** aiuta a valutare le analisi statistiche.

Le **medie** indicano se i valori di glicemia di una persona sono elevati o bassi.

La **deviazione standard** indica la variabilità dei valori di glicemia ottenuti. Più è elevata, più ampio sarà l'intervallo di valori di glicemia e viceversa

Hirsch I et al, Diabetes Technol Ther 2008; 10 (6): 419-39
Bode B, US Endocrinology 2009; 4 (2): 67-70

Significato dell'automonitoraggio glicemico in Educazione Terapeutica

E' uno strumento di condivisione che permette una relazione efficace

E' un terreno di confronto e di scambio di idee, valutazioni, proposte in posizione paritaria

Automonitoraggio glicemico e Responsabilità del sanitario: intervento di Educazione Terapeutica

Competenze cognitive

Significato della registrazione dei dati

Modalità di interpretazione dei dati

Orientamento nelle scelte terapeutiche

Competenze tecniche

Modalità di esecuzione corretta

Registrazione dei dati (diario elettronico?)


il percorso è affidato
all'educazione e
rispetto degli utenti

Grazie