Pro e contro in tema di monitoraggio della glicemia in MDI

FLASH GLUCOSE MONITORING

VS

MONITORAGGIO CONTINUO DEL GLUCOSIO

CGM

Novella Rapini

UC Diabetologia

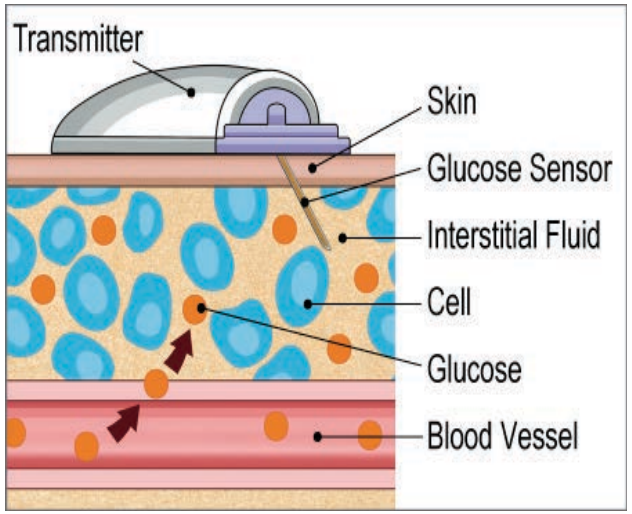
OPBG

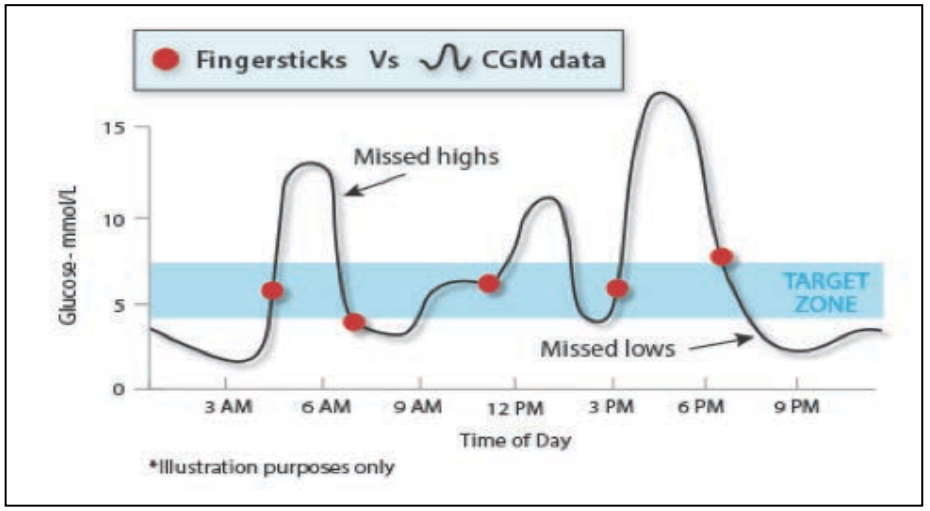
Ia dr.ssa Rapini Novella dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:

MEDTRONIC

Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, ecc.).

Vantaggi del monitoraggio continuo della glicemia



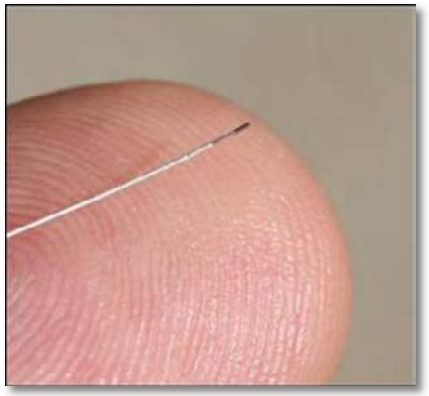


1. Ipoglicemie asintomatiche e notturne
2. Fenomeno alba
3. Iperglicemie post prandiali

→ **Azioni correttive**

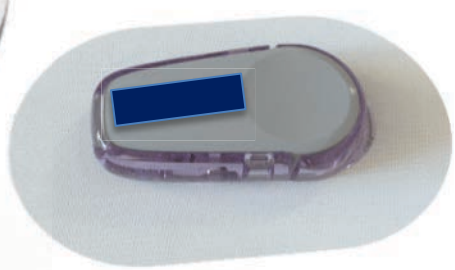
Il sistema CGM

Sensore +
Algoritmo



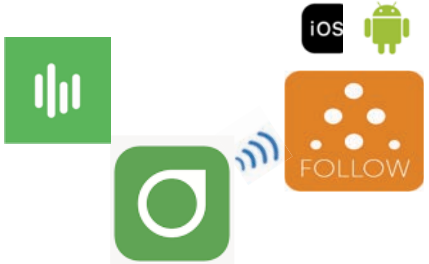
Applicatore
automatico

Trasmettitore



Ricevitore

Smart device



Il sistema CGM

ACCURATEZZA DI MISURA

Misurazione delle prestazioni	Totale popolazione	Adulto (>18 anni)	Pediatria (6-17 anni)
Accuratezza complessiva (MARD), 40-400 mg/dl[1]	9.0%	9.8% (addome)	7.7% (addome o alto gluteo)
Giorno 1 %MARD	9.3%		
Giorno 10 %MARD	9.0%		

- Durata del sensore: 10 giorni
- Calibrazione non necessaria
- Approvato per prendere decisioni terapeutiche

[1] Performance of a Factory-Calibrated Real-Time Continuous Glucose Monitoring System Utilizing an Automated Sensor Applicator, DIABETES TECHNOLOGY & THERAPEUTICS, Volume 20, Number 6, 2018

ACCURATEZZA

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 20, Number 6, 2018
© Mary Ann Liebert, Inc.
DOI: 10.1089/dia.2018.0143

DTT

ORIGINAL ARTICLE

Performance of a Factory-Calibrated Real-Time Continuous Glucose Monitoring System Utilizing an Automated Sensor Applicator

Viral N. Shah, MD,[1] Lori M. Laffel, MD, MPH,[2] R. Paul Wadwa, MD,[1] and Satish K. Garg, MD[1]

TABLE 3. CONTINUOUS GLUCOSE MONITORING PERFORMANCE ACROSS DAYS OF SENSOR WEAR

Clinic session day	*Matched pairs* (n)	*%15/15* (%)	*%20/20* (%)	*%30/30* (%)	*MARD* (%)
Day 1	719	81.5	92.2	99.0	9.3
Day 2	664	84.0	92.3	100.0	8.4
Days 4–5	880	85.8	95.5	99.2	9.4
Day 7	588	82.1	97.3	99.8	8.7
Day 10	681	82.4	92.5	99.1	9.0

Technology Report

Performance of a Factory-Calibrated, Real-Time Continuous Glucose Monitoring System in Pediatric Participants With Type 1 Diabetes

Journal of Diabetes Science and Technology
1–5

DOI: 10.1177/1932296818798816
journals.sagepub.com/home/dst
SAGE

John B. Welsh, MD, PhD[1], Xiaohe Zhang, MS[1], Sarah A. Puhr, PhD[1], Terri Kang Johnson, PhD[1], Tomas C. Walker, DNP, CDE[1], Andrew K. Balo, BS[1], and David Price, MD[1]

Table 1. Point and Percentage Accuracy in Pediatric Participants Overall and by Clinic Session Day.

Clinic session day	Matched pairs (n)	%15/15 (%)	%20/20 (%)	%30/30 (%)	%40/40 (%)	MAD (mg/dL)	MARD (%)
Overall	1387	91.1	96.2	99.6	99.9	11.1	7.7
Day 1	253	78.3	92.1	98.8	100.0	15.8	10.5
Day 2	260	94.2	100.0	100.0	100.0	13.4	7.8
Days 4-5	322	95.7	98.8	99.7	99.7	8.8	7.2
Day 7	253	97.2	99.2	100.0	100.0	7.9	6.2
Day 10	299	89.3	91.0	99.3	100.0	10.5	7.1

Il SISTEMA GUARDIAN CONNECT

- Durata del sensore: 7 giorni
- Calibrazione necessaria 3-4 volte al giorno

ACCURATEZZA

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 20, Number 9, 2018

DOI: 10.1089/dia.2018.0109

DTT

ORIGINAL ARTICLE

Accuracy of a Fourth-Generation Continuous Glucose Monitoring System in Children and Adolescents with Type 1 Diabetes

Robert H. Slover, MD,[1] Jeanie B. Tryggestad, MD,[2] Linda A. DiMeglio, MD, MPH,[3] Larry A. Fox, MD,[4] Bruce W. Bode, MD,[5] Timothy S. Bailey, MD,[6] Ronald Brazg, MD,[7] Mark P. Christiansen, MD,[8] Jennifer L. Sherr, MD, PhD,[9] Eva Tsalikian, MD,[10] Kevin B. Kaiserman, MD,[11] Ashley Sullivan, MSc,[12] Suiying Huang, MSc,[12] John Shin, PhD, MBA,[12] Scott W. Lee, MD,[12] and Francine R. Kaufman, MD[12]

TABLE 2. GUARDIAN™ CONTINUOUS GLUCOSE MONITORING SYSTEM ANALYTICAL ACCURACY DURING FREQUENT SAMPLE TESTING, BY DAY OF SENSOR WEAR, CALIBRATION, AND DEVICE

		Minimum calibrations[a]		*One additional calibration*[b]	
FST day	*Sensor location*	N	*MARD, %*	N	*MARD, %*
Day 1	Guardian Connect System	1257	12.0±11.8	1109	11.1±11.0
	GSR	1116	12.9±12.4	1123	12.6±12.3
Day 3	Guardian Connect System	1049	8.9±7.2	1044	8.8±7.0
	GSR	961	8.9±7.6	960	8.9±7.6
Day 7	Guardian Connect System	796	11.8±12.2	737	10.2±9.0
	GSR	547	11.2±10.4	547	10.7±9.8
Overall	Guardian Connect System	3102	10.9±10.7	2890	10.1±9.3
	GSR	2624	11.1±10.6	2630	10.9±10.4

L'utilizzo del CGM in terapia multi-iniettiva

BMJ

BMJ 2011;343:d3805 doi: 10.1136/bmj.d3805

RESEARCH

Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data

Tables

Table 1| **Characteristics of trials included in meta-analysis**

Study	No randomised	No analysed	Dropout rate (%)	Mean age (years)	Mean baseline HbA1c (%)	Mean diabetes duration (years)	Study duration (weeks)	Insulin delivery
Deiss et al 2006[3]	162	156	3.7	26.8	9.56	—*	13	Continuous subcutaneous infusion or multiple daily injections
Hirsch et al 2008[4]	146	138	5.5	33.1	8.44	18.7	26	Continuous subcutaneous infusion
JDRF 2008 (primary)[5]	322	317	1.6	23.5	7.84	12.1	26	Continuous subcutaneous infusion or multiple daily injections
JDRF 2009 (secondary)[6]	129	127	1.6	30.7	6.45	34.6	26	Continuous subcutaneous infusion or multiple daily injections
O'Connell et al 2009[7]	62	55	11.3	23.2	7.40	10.2	13	Continuous subcutaneous infusion
Raccah et al 2009[8]	132	115	12.9	28.5	9.20	28.4	26	Continuous subcutaneous infusion

JDRF=Juvenile Diabetes Research Foundation.

*Not given in published paper.

L'utilizzo del CGM in terapia multi-iniettiva

Research

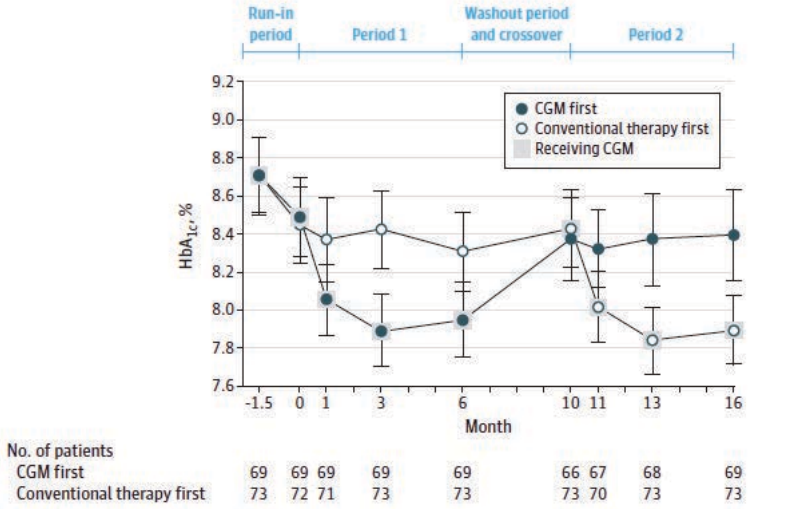
JAMA | Original Investigation

Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections

The GOLD Randomized Clinical Trial

Marcus Lind, MD, PhD; William Polonsky, PhD; Irl B. Hirsch, MD; Tim Heise, MD; Jan Bolinder, MD, PhD; Sofia Dahlqvist; Erik Schwarz, MD, PhD; Arndís Finna Ólafsdóttir, RN; Anders Frid, MD, PhD; Hans Wedel, PhD; Elsa Ahlén, MD; Thomas Nyström, MD, PhD; Jarl Hellman, MD

Figure 2. HbA_{1c} Values at Inclusion, Randomization, and During the 2 Different Periods of Treatment



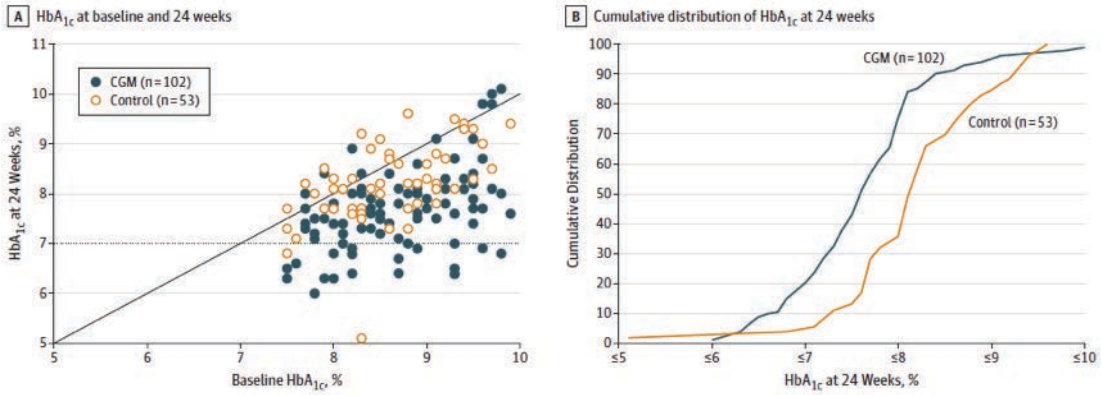
Research

JAMA | Original Investigation

Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections

The DIAMOND Randomized Clinical Trial

Figure 2. Hemoglobin A_{1c} Values at Baseline and 24 Weeks, by Group



L'utilizzo del CGM in terapia multi-iniettiva

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*

Durata dello studio: 26 settimane

>25 aa

15-24aa

8-14 aa

- HbA1c: no differenze nei gruppi adolescenti e pediatrici
- **Utilizzo del sensore basso nel gruppo degli adolescenti**
- Non differenze tra chi utlizzava pompa rispetto alla MDI (ma con MDI pochi pazienti)

L'utilizzo del CGM in terapia multi-iniettiva

Clinical Care/Education/Nutrition
ORIGINAL ARTICLE

A Pilot Study of the Continuous Glucose Monitoring System

Clinical decisions and glycemic control after its use in pediatric type 1 diabetic subjects

2030 DIABETES CARE, VOLUME 24, NUMBER 12, DECEMBER 2001

47 patients with a mean HbA1c value of 8.61.6% (mean age **11.84** years, youngest 2.7 years, and diabetes duration 5.53.5 years):

- **three to four insulin injections/day (n24)**
- Insulin pump therapy (n 23)
- CGMS for a mean of 69.5 28 h.

Table 2 —*HbA_{1c} for all subjects and those on CSII and injections*

Time from baseline (months)	All	CSII	Injections
−3	8.7 ± 1.6	8.5 ± 1.6	8.9 ± 1.6
0	8.6 ± 1.5	8.4 ± 1.7	8.8 ± 1.4
+3	8.4 ± 1.3	8.2 ± 1.3	8.5 ± 1.3
+6	8.3 ± 1.3	8.1 ± 1.3	8.5 ± 1.4

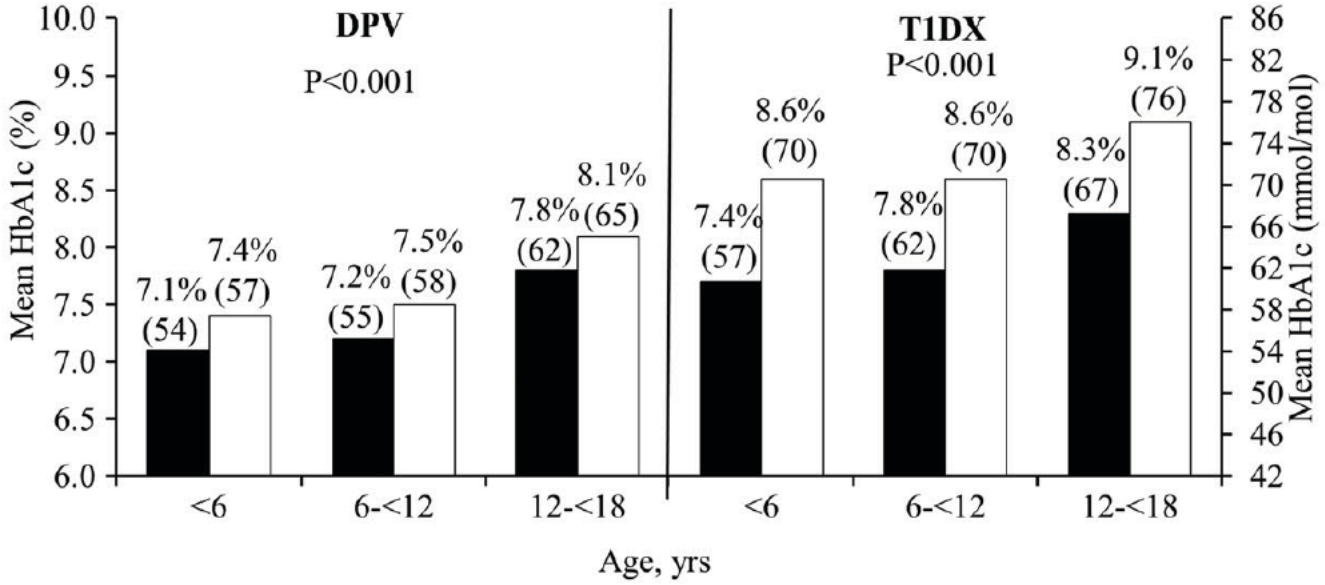
Data are means ± SE. Repeat measures of ANOVA: type III sum of squares = 4.509; df = 2.185; mean square = 2.064; $F = 3.262$; $P = 0.038$.

Night time hypoglycemia→decrease evening intermediate-acting insulin on patients on injection therapy

High premeal and post meal pattern→ increasing one or more basal and bolus insulin dosage in 87 and 70% of subjects, respectively

Continuous glucose monitoring and glycemic control among youth with type 1 diabetes: International comparison from the T1D Exchange and DPV Initiative

Daniel J. DeSalvo[1] | Kellee M. Miller[2] | Julia M. Hermann[3,4] | David M. Maahs[5] | Sabine E. Hofer[6] | Mark A. Clements[7] | Eggert Lilienthal[8] | Jennifer L. Sherr[9] | Martin Tauschmann[10] | Reinhard W. Holl[3,4] | the T1D Exchange and DPV Registries



Pediatric Diabetes. 2018;19:1271–1275.

L'utilizzo del CGM in terapia multi-iniettiva

Improving the Clinical Value and Utility of CGM Systems: Issues and Recommendations

A Joint Statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group

John R. Petrie,[1] Anne L. Peters,[2] Richard M. Bergenstal,[3] Reinhard W. Holl,[4] G. Alexander Fleming,[5] and Lutz Heinemann[6]

https://doi.org/10.2337/dci17-0043

In children and adolescents, achieving adequate adherence remains a significant barrier, although usability has improved with current-generation CGM devices in this age-group [2b].

Diabetes Care Publish Ahead of Print, published online October 25, 2017

Utilizzo del CGM e TIR

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

https://doi.org/10.2337/dci19-0028

Table 2—Standardized CGM metrics for clinical care: 2019

1. Number of days CGM worn (recommend 14 days) (42,43)	
2. Percentage of time CGM is active (recommend 70% of data from 14 days) (41,42)	
3. Mean glucose	
4. Glucose management indicator (GMI) (75)	
5. Glycemic variability (%CV) target ≤36% (90)*	
6. Time above range (TAR): % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2
7. Time above range (TAR): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	Level 1
8. Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	In range
9. Time below range (TBR): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	Level 1
10. Time below range (TBR): % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2
Use of Ambulatory Glucose Profile (AGP) for CGM report	

CV, coefficient of variation. *Some studies suggest that lower %CV targets (<33%) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas (45,90,91).

Utilizzo del CGM e TIR

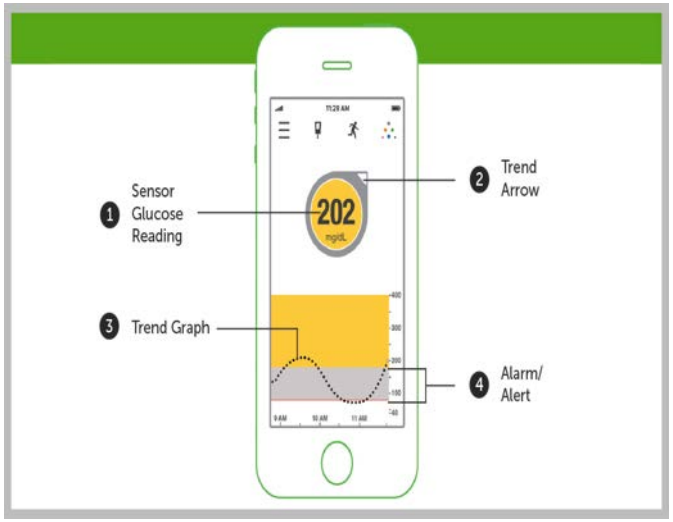
Table 3—Guidance on targets for assessment of glycemic control for adults with type 1 or type 2 diabetes and older/high-risk individuals

	TIR		TBR		TAR	
Diabetes group	% of readings; time per day	Target range	% of readings; time per day	Below target level	% of readings; time per day	Above target level
Type 1*/type 2	>70%; >16h, 48 min	70–180 mg/dL (3.9–10.0 mmol/L)	<4%; <1 h <1%; <15 min	<70 mg/dL (<3.9 mmol/L) <54 mg/dL (<3.0 mmol/L)	<25%; <6 h <5%; <1 h, 12 min	>180 mg/dL (>10.0 mmol/L) >250 mg/dL (>13.9 mmol/L)
Older/high-risk# type 1/type 2	>50%; >12 h	70–180 mg/dL (3.9–10 mmol/L)	<1%; <15 min	<70 mg/dL (<3.9 mmol/L)	<10%; <2 h, 24 min	>250 mg/dL (>13.9 mmol/L)

Each incremental 5% increase in TIR is associated with clinically significant benefits for individuals with type 1 or type 2 diabetes (26,27). *For age <25 years, if the A1C goal is 7.5%, set TIR target to approximately 60%. See the section CLINICAL APPLICATION OF TIME IN RANGES for additional information regarding target goal setting in pediatric management. #See the section OLDER AND/OR HIGH-RISK INDIVIDUALS WITH DIABETES for additional information regarding target goal setting.

Punti di forza nell'utilizzo del monitoraggio continuo della glicemia in MDI

1. **Glucosio attuale**
2. **Grafico trend**
3. **Utilizzo delle frecce di tendenza**
4. **Utilizzo del sistema predittivo**



1. **Educazione del paziente**

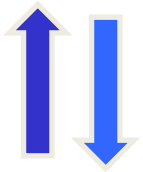
1. **Analisi dei dati**

FRECCE DI TENDENZA

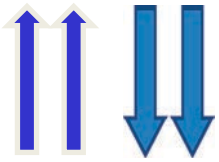
	Indication
→	**Constant:** Glucose is steady – not increasing/decreasing more than 1 md/dL per minute
↗	**Slowly Rising**: Glucose is rising 1-2 mg/dL per minute
↑	**Rising**: Glucose is rising 2-3 mg/dL per minute
↑↑	**Rapidly Rising**: Glucose is rising more than 3 mg/dL per minute
↘	**Slowly Falling**: Glucose is falling 1-2 mg/dL per minute
↓	**Falling**: Glucose is falling 2-3 mg/dL per minute
↓↓	**Rapidly Falling**: Glucose is falling more than 3 mg/dL per minute

non più di 30 mg/dl in 30 min

30-60 mg/dl in 30 min



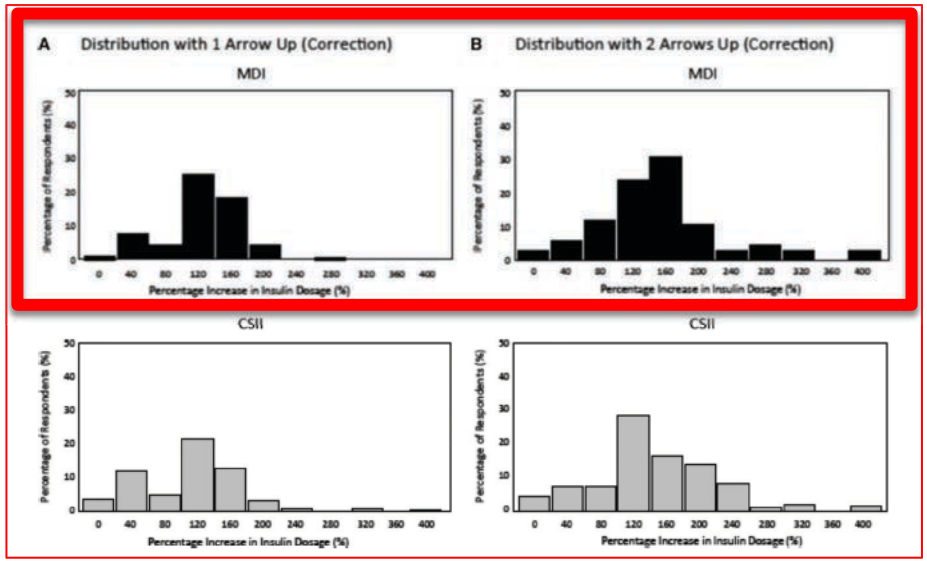
60-90 mg/dl in 30 min

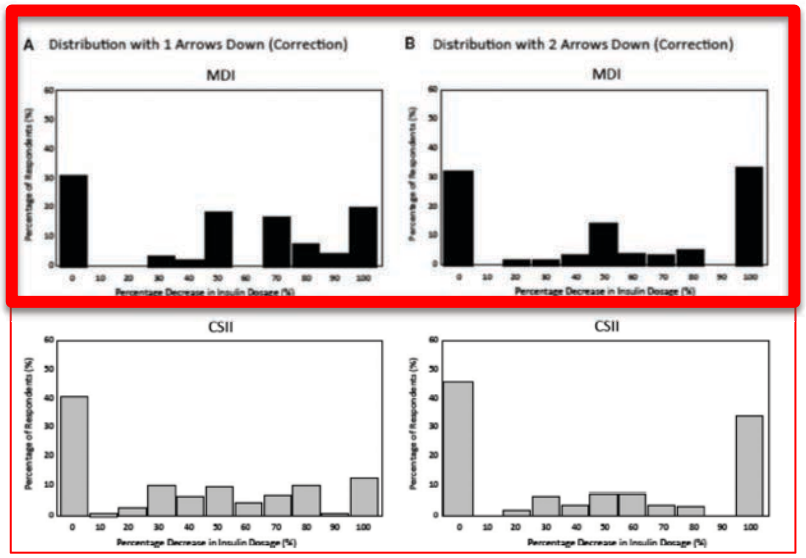


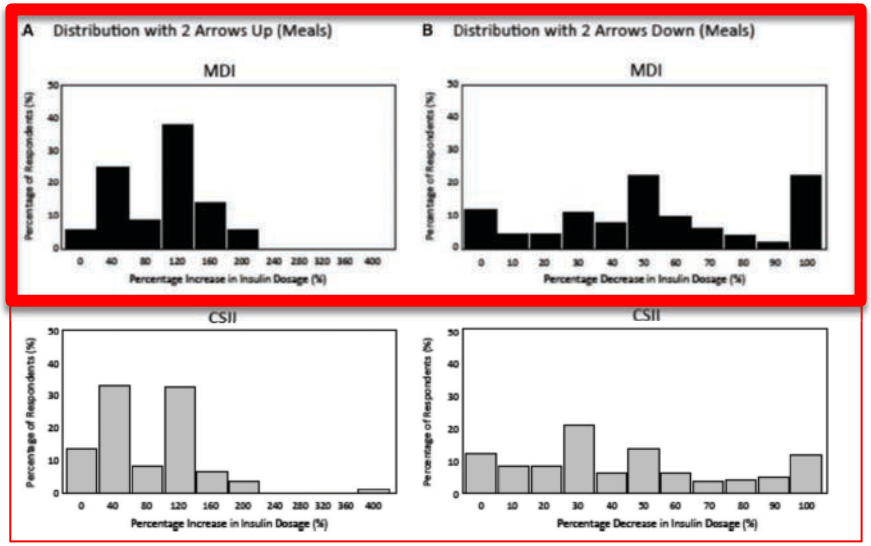
più di 90 mg/dl in 30 min

Pettus J et al., J Diab Techn Ther 2016

FRECCE DI TENDENZA

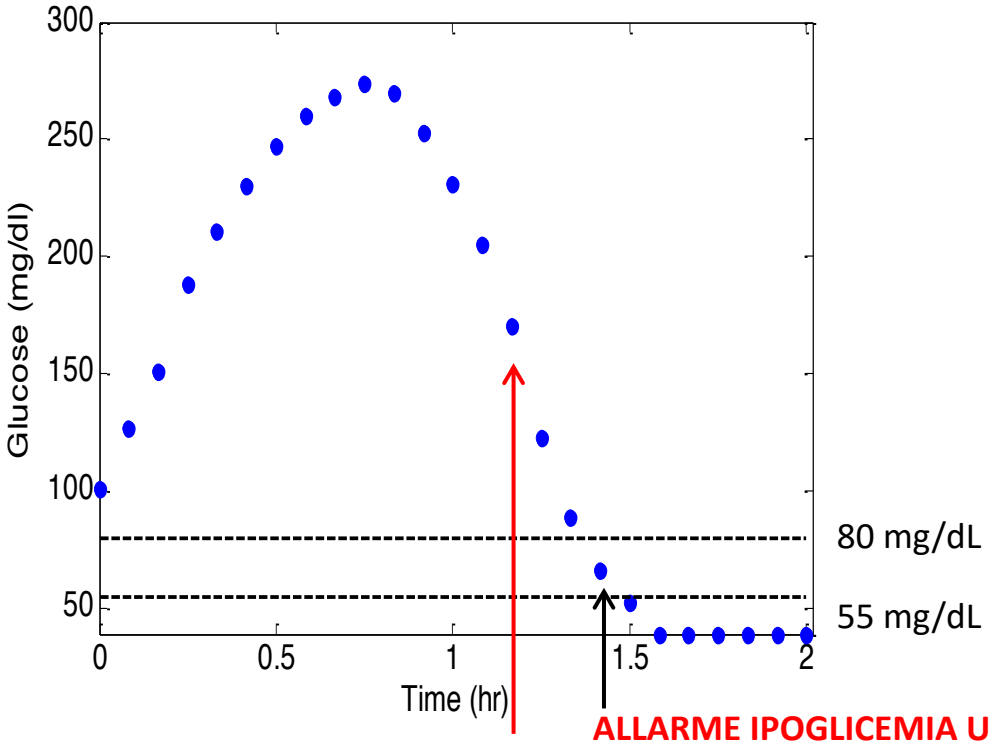






Pettus J et al., J Diab Techn Ther 2016

Il sistema CGM



ALLARME IPOGLICEMIA URGENTE Soglia di allarme= preavviso di 5 minuti

AVVISO IPOGLICEMIA URGENTE IMMINENTE

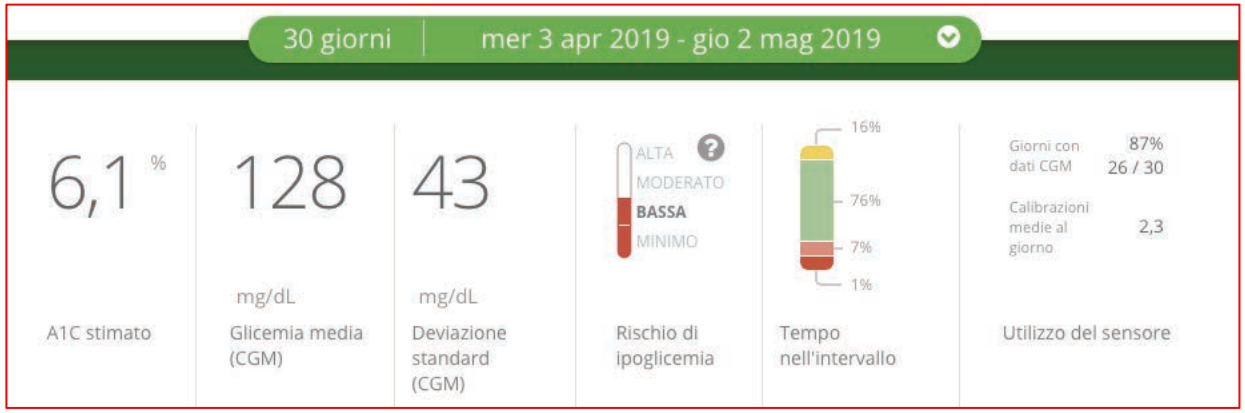
comunica che la glicemia sta scendendo rapidamente e arriverà a un valore inferiore o uguale a 55 mg/dL entro 20 minuti a prescindere dal valore attuale

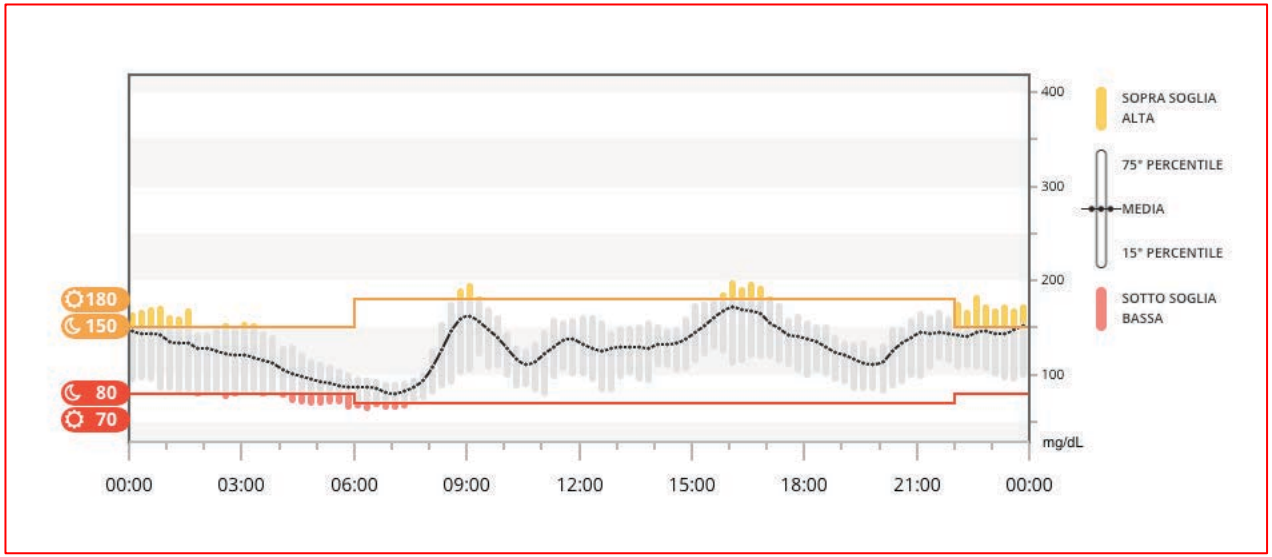
OPZIONI DI AVVISO GUARDIAN CONNECT

1 IMPOSTAZIONI AVVISO GLUCOSIO ALTO

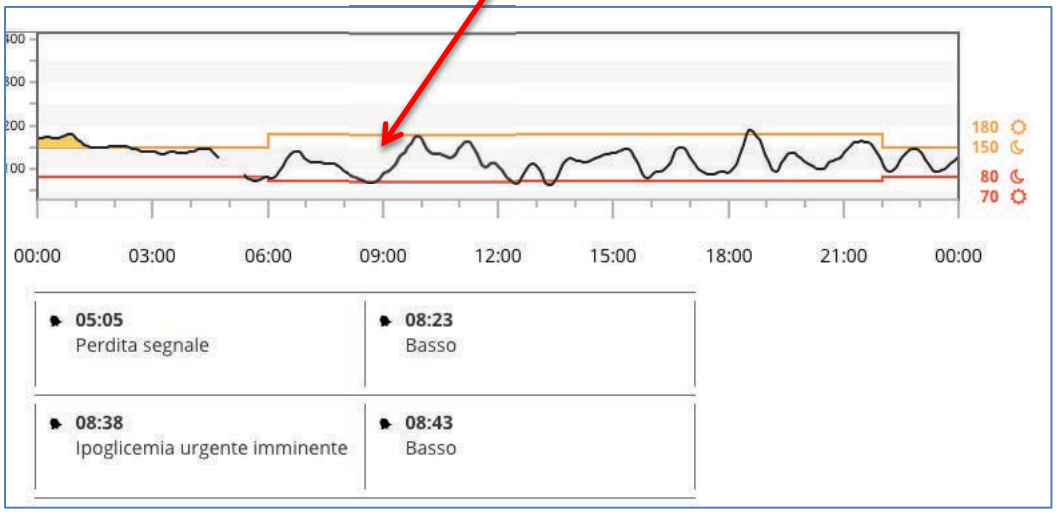
2 IMPOSTAZIONI AVVISO GLUCOSIO BASSO

Analisi dati: utilizzo del Clarity





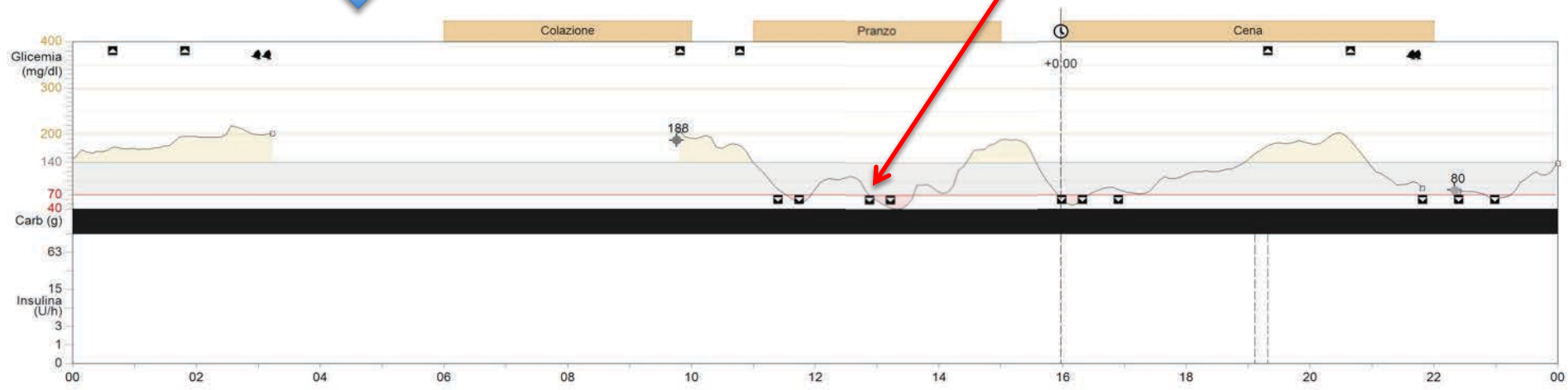
Analisi dati: utilizzo del Clarity



PIATTAFORMA CARELINK™

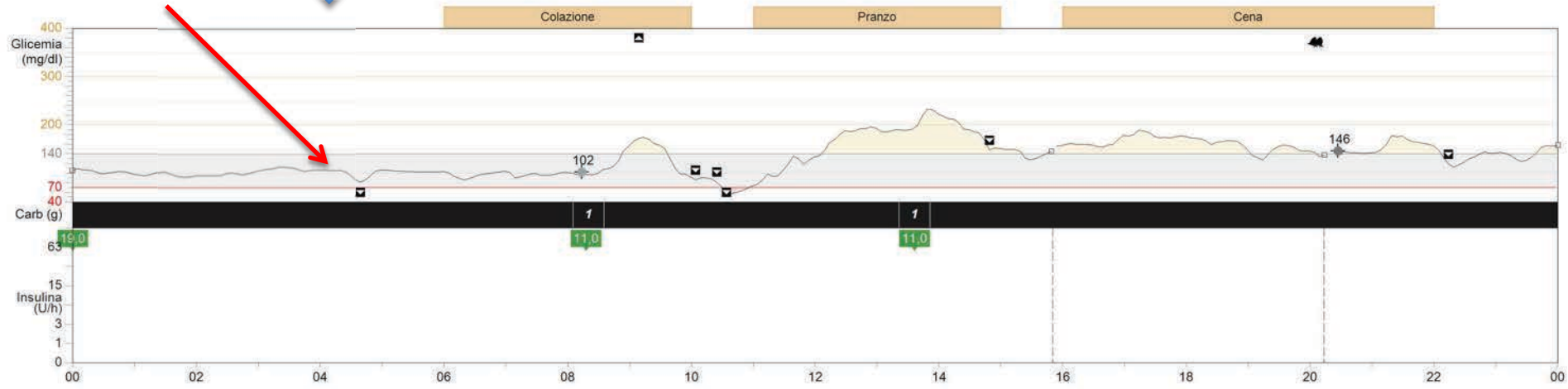
Da sensore 78

Intervento



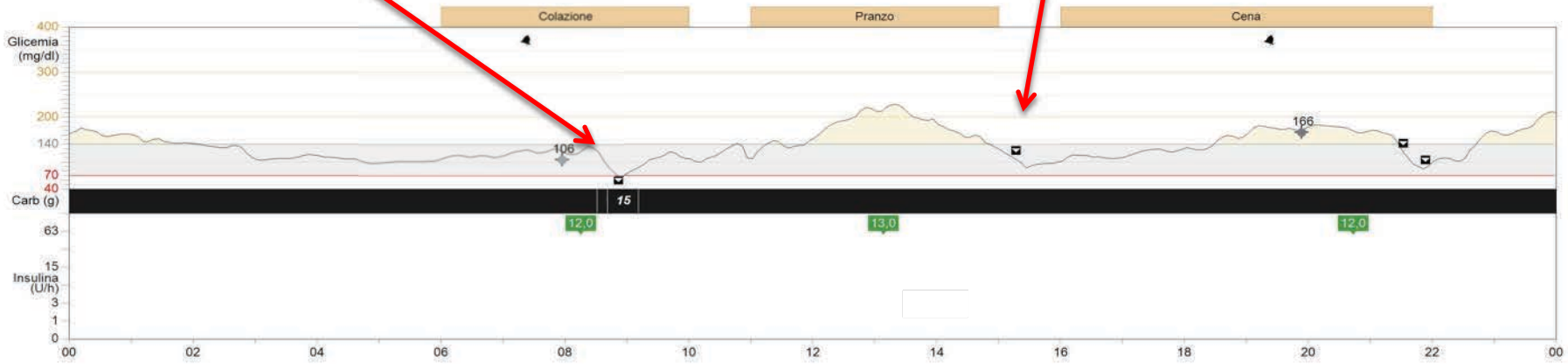
Da sensore 98

Intervento con CHO

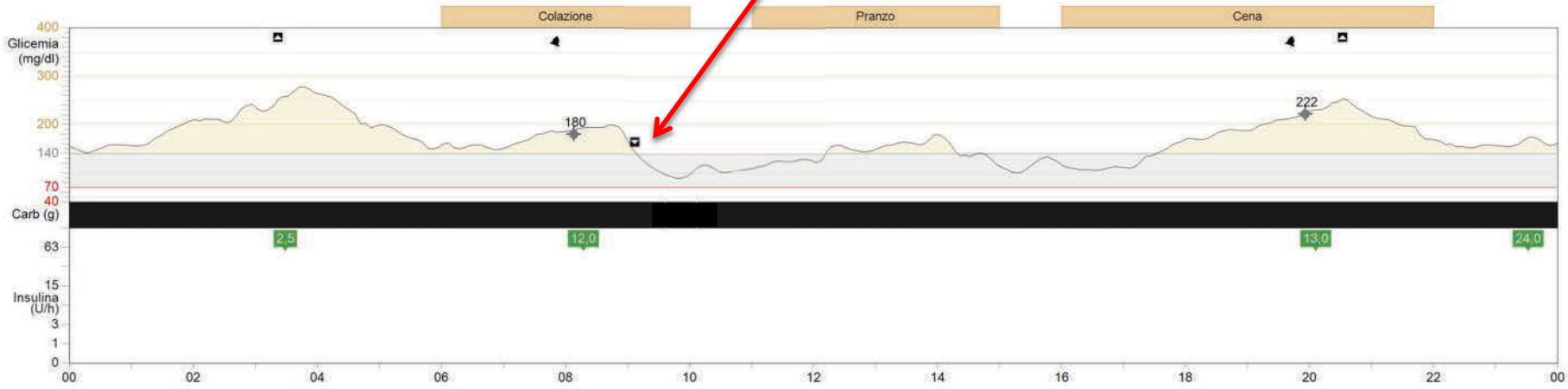


Allarme ipo
intervento→15 gr CHO

Allarme predittivo ipo
intervento→5 gr CHO



Allarme predittivo ipo
intervento→5 gr CHO



Esempi pratici

Da sensore 98 ↓ Intervento

Allarme predittivo ipo
intervento→5 gr CHO

Punti di forza e "non" nell'utilizzo del monitoraggio continuo della glicemia in terapia multi-iniettiva:

Continuous Glucose Monitoring in Pediatrics: The Gap between Potential Benefits and the Reality of Utility

Regina L. Taddeo, MA, RN, CDE, CPT, Joanne T. Moser, RN, MSN, CRNP,
Pantea P. Minnock, RN, MSN, CRNP, CCRP

- Without proper education, this tremendous quantity of blood glucose data can be viewed as information overload
- Alarm fatigue
- Inappropriate overtreatment
- Exacerbation of family conflicts ant tensions
- Some children have reported feeling "spied on"
- Frustration with having their blood glucose be the absolute center of attention all day

Pediatric Endocrinology Reviews (PER) ● Volume 14 ● Supplement 2 ● June 2017

Conclusioni

- L'utilizzo del CGM in pazienti che utilizzano MDI puo' migliorare il controllo glico-metabolico ed ottimizzare la terapia
- E' importante utilizzare lo strumento nel modo corretto per avere informazioni attendibili→ calibrazione, interpretazione delle frecce, utilizzo degli allarmi, sistemi predittivi
- Educazione del paziente da parte del team
- **Analisi critica dei dati insieme al paziente attraverso lo scarico dati**
- Non sottovalutare gli aspetti psicologici

Grazie
per
l'attenzione!!